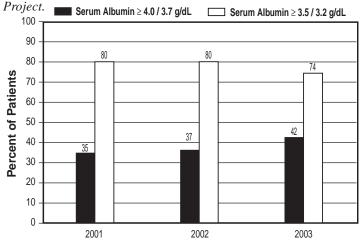
# 2. Findings for October-December 2003 compared to previous study periods (for patients < 18 years)

#### a. Findings for patients 0 to < 12 years

There has been little change in the percent of pediatric patients aged 11 years or younger achieving mean serum albumin targets from late 2001 to late 2003 (FIGURE 76).

Figure 76: Percent of pediatric (aged 0 to < 12 years) in-center hemodialysis patients with mean serum albumin  $\geq 4.0/3.7\,$  g/dL (BCG/BCP) $^{\wedge}$  and  $\geq 3.5/3.2\,$  g/dL (BCG/BCP), October-December 2003 compared to previous study periods. 2004 ESRD CPM

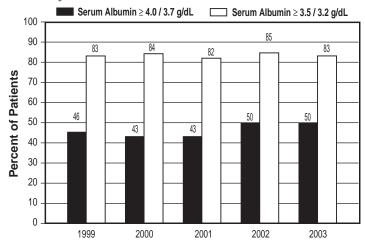


^BCG/BCP = bromcresol green/bromcresol purple laboratory methods. Note: To convert serum albumin conventional units of g/dL to SI units (gL), multiply by 10.

#### b. Findings for patients 12 to < 18 years

There was no clinically important change or improvement in the percent of pediatric patients aged 12 to < 18 years achieving mean serum albumin targets from late 1999 to late 2003 (FIG-URE 77).

Figure 77: Percent of pediatric (aged 12 to < 18 years) incenter hemodialysis patients with mean serum albumin  $\geq 4.0/3.7$  g/dL (BCG/BCP)^ and  $\geq 3.5/3.2$  g/dL (BCG/BCP), October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



^BCG/BCP = bromcresol green/bromcresol purple laboratory methods. Note: To convert serum albumin conventional units of g/dL to SI units (gL), multiply by 10.

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### IX. List of Tables and Figures

Ta	ble Title	Page
1.	Number of adult in-center hemodialysis patients in each Network in December 2003, sample size and response rate for the 2004 ESRD CPM Project	8
2.	Characteristics of adult in-center hemodialysis patients in the 2004 ESRD CPM Project compared to those of all in-center hemodialysis patients in the US in 2002.	9
3.	Number of adult peritoneal dialysis patients in each Network in December 2003, sample size and response rate for the 2004 ESRD CPM Project.	9
4.	Characteristics of adult peritoneal dialysis patients in the 2004 ESRD CPM Project compared to those of all peritoneal dialysis patients in the US in 2002.	10
5.	Characteristics of pediatric (aged < 18 years) in-center hemodialysis patients in the 2004 ESRD CPM Project.	11
6.	Mean delivered calculated, single session spKt/V and percent of adult in-center hemodialysis patients with mean delivered calculated, single session spKt/V $\geq$ 1.2 and $\geq$ 1.3 by patient characteristics, October-December 2003. 2004 ESRD CPM Project.	22
7.	Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session spKt/V $\geq$ 1.2, by gender, race, ethnicity, and Network, October-December 2003. 2004 ESRD CPM Project.	24
8.	Vascular access type for incident and all adult in-center hemodialysis patients during the last hemodialysis session of the study period, by selected patient characteristics, October-December 2003. 2004 ESRD CPM Project.	26
9.	Percent of all adult in-center hemodialysis patients with an AV fistula access on their last hemodialysis session during October–December 2003, by gender, race, ethnicity, age, cause of ESRD, and Network. 2004 ESRD CPM Project.	28
10.	Percent of all adult in-center hemodialysis patients with a catheter access on their last hemodialysis session during October–December 2003, by gender, race, ethnicity, age, cause of ESRD, and Network. 2004 ESRD CPM Project.	29
11.	Reasons for catheter placement in adult in-center hemodialysis patients using catheters on their last hemodialysis session during October-December 2003. 2004 ESRD CPM Project.	30
12.	Mean hemoglobin values (g/dL) for adult in-center hemodialysis patients in the US, by patient characteristics, October–December 2003. 2004 ESRD CPM Project.	33
13.	Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by gender, race, ethnicity, age, access, mean serum albumin, and Network, October-December 2003. 2004 ESRD CPM Project.	34
14.	Regional variation for various anemia management measures for adult in-center hemodialysis patients including the percent of patients with mean hemoglobin $\geq$ 11 g/dL, mean hemoglobin (g/dL), and mean serum albumin $\geq$ 4.0 BCG for these patients nationally and by Network, October-December 2003. 2004 ESRD CPM Project.	37
15.	Percent of adult in-center hemodialysis patients with mean serum albumin values $\geq$ 4.0/3.7 g/dL (BCG/BCP) and $\geq$ 3.5/3.2 g/dL (BCG/BCP) in the US, by patient characteristics, October-December 2003. 2004 ESRD CPM Project.	39
16.	Percent of adult in-center hemodialysis patients with mean serum albumin ≥ 4.0/3.7 g/dL (BCG/BCP method) by gender, race, ethnicity, age, cause of ESRD, and Network, October-December 2003. 2004 ESRD CPM Project	t. 41

Та	ble Title	Page
17.	Percent of adult CAPD patients with mean (± SD) weekly adequacy values meeting 2000 NKF-K/DOQI guidelines and median adequacy values, by transporter type (4 hr. D/P Cr Ratio), October 2003–March 2004. 2004 ESRD CPM Project.	44
18	. Percent of adult cycler patients with mean ( $\pm$ SD) weekly adequacy values meeting 2000 NKF-K/DOQI guidelines and median adequacy values, October 2003–March 2004. 2004 ESRD CPM Project.	44
19	. Mean hemoglobin values (g/dL) for adult peritoneal dialysis patients, by patient characteristics, October 2003-March 2004. 2004 ESRD CPM Project.	47
20	. Percent of adult peritoneal dialysis patients with mean serum albumin values ≥ 4.0/3.7 g/dL (BCG/BCP) and ≥ 3.5/3.2 g/dL (BCG/BCP) in the US, by patient characteristics, October 2003-March 2004. 2004 ESRD CPM Project.	49
21	. Mean delivered calculated, single session spKt/V for all pediatric (aged < 18 years) in-center hemodialysis patients and percent of patients with mean spKt/V ≥ 1.2, by patient characteristics, October-December 2003. 2004 ESRD CPM Project.	50
22	Vascular access type for all pediatric (aged < 18 years) in-center hemodialysis patients on their last hemodialysis session during October-December 2003, by selected patient characteristics. 2004 ESRD CPM Project.	52
23	Reasons for catheter placement in all pediatric (aged < 18 years) in-center hemodialysis patients using catheters on their last hemodialysis session during October-December 2003. 2004 ESRD CPM Project.	53
24	. Mean hemoglobin values (g/dL) and distribution of hemoglobin values for all pediatric (aged < 18 years) in-center hemodialysis patients, by patient characteristics, October-December 2003. 2004 ESRD CPM Project.	55
25	Percent of all pediatric (aged < 18 years) in-center hemodialysis patients with mean serum albumin values $\geq$ 4.0/3.7 g/dL (BCG/BCP), and $\geq$ 3.5/3.2 g/dL (BCG/BCP), by patient characteristics, October-December 2003. 2004 ESRD CPM Project.	58
Fi	gure Title	Page
1.	Geographical boundaries of the 18 ESRD Network Organizations (map).	i
2.	Vascular access type for all adult in-center hemodialysis patients on their last hemodialysis session during the study period. 2004 ESRD CPM Project.	15
3.	Percent of adult peritoneal dialysis patients with total solute clearance for urea and creatinine measured at least once during the study period (PD Adequacy CPM I) and with total solute clearance calculated in a standard way (PD Adequacy CPM II), October 2003-March 2004 compared to previous study periods. 2004 ESRD CPM Project.	15
4.	Percent of adult peritoneal dialysis patients meeting 1997 NKF-DOQI guidelines for weekly Kt/V <sub>urea</sub> and weekly creatinine clearance (PD Adequacy CPM III). 2004 ESRD CPM Project.	15
5.	Percent of adult in-center hemodialysis patients with mean delivered calculated, single session single pool (sp)Kt/V $\geq$ 1.2 in October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	15
6.	Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	16
7.	Distribution of mean hemoglobin values for adult in-center hemodialysis patients, October-December 2003	

Fiç	gure Title	Page
8.	Percent of adult peritoneal dialysis patients with mean hemoglobin ≥ 11 g/dL, October 2003-March 2004 compared to previous study periods. 2004 ESRD CPM Project.	16
9.	Distribution of mean hemoglobin values for adult peritoneal dialysis patients, October 2003-March 2004 compared to previous study periods. 2004 ESRD CPM Project.	16
10.	Distribution of mean delivered calculated, single session spKt/V values for pediatric (aged < 18 years) in-center hemodialysis patients, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	17
11.	Vascular access type for pediatric (aged < 18 years) in-center hemodialysis patients on their last hemodialysis session during the study period. 2004 ESRD CPM Project.	17
12.	Distribution of mean hemoglobin values for pediatric (aged < 18 years) in-center hemodialysis patients, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	17
13.	Distribution of mean delivered calculated, single session spKt/V values for adult in-center hemodialysis patients, October–December 2003. 2004 ESRD CPM Project.	22
14.	Distribution of mean delivered blood pump flow rates 60 minutes into the dialysis session for adult in-center hemodialysis patients, by access type, October–December 2003. 2004 ESRD CPM Project.	22
15.	Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session spKt/V $\geq$ 1.2, by Network, October–December 2003 2004 ESRD CPM Project.	23
16.	Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session spKt/V $\geq$ 1.2, by Network, October–December 2003. 2004 ESRD CPM Project.	23
17.	Percent of adult male in-center hemodialysis patients with mean delivered, single session spKt/V $\geq$ 1.2, by race, October–December 2003 compared to previous study periods. 2004 ESRD CPM Project.	23
18.	Percent of adult female in-center hemodialysis patients with mean delivered, single session spKt/V $\geq$ 1.2, by race, October–December 2003 compared to previous study periods. 2004 ESRD CPM Project.	25
19.	Percent of adult in-center hemodialysis patients dialyzed by dialyzer KUf category, October–December 2003 compared to previous study periods. 2004 ESRD CPM Project.	25
20.	Distribution of mean dialysis session length (minutes), October–December 2003 compared to previous study periods. 2004 ESRD CPM Project.	25
21.	Percent of all adult in-center hemodialysis patients dialyzed with a catheter continuously for 90 days or longer as their vascular access on their last hemodialysis session during October-December 2003, by patient characteristics. 2004 ESRD CPM Project.	26
22.	Percent of all adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2003, by patient characteristics. 2004 ESRD CPM Project.	27
23.	Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October–December 2003, by patient characteristics. 2004 ESRD CPM Project.	27
24.	Percent of all adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October–December 2003, by Network. 2004 ESRD CPM Project.	27
25.	Percent of incident adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October–December 2003, by Network. 2004 ESRD CPM Project.	27
26.	Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October–December 2003, by Network, 2004 ESRD CPM Project.	27

Fig	gure Title	Page
27.	Percent of all adult in-center hemodialysis patients dialyzed with a catheter continuously for 90 days or longer as their vascular access on their last hemodialysis session during October–December 2003, by Network. 2004 ESRD CPM Project.	27
28.	Percent of incident adult in-center hemodialysis patients with different types of vascular access upon initiation of a maintenance course of hemodialysis and 90 days later.2004 ESRD CPM Project.	30
29.	Percent of adult in-center hemodialysis patients (all and incident) dialyzed with a catheter as their access on their last hemodialysis session during October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	31
30.	Percent of adult in-center hemodialysis patients (all and incident) dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	31
31.	Types of stenosis monitoring reported for adult in-center hemodialysis patients with either an AV fistula or an AV graft as their vascular access on their last hemodialysis session during October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	31
32.	Distribution of mean hemoglobin values for adult in-center hemodialysis patients in the US, by race, October–December 2003. 2004 ESRD CPM Project.	32
33.	Percent of adult in-center hemodialysis patients with mean hemoglobin < 10 g/dL, by Network, October–December 2003. 2004 ESRD CPM Project.	33
34.	Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by Network, October–December 2003. 2004 ESRD CPM Project.	35
35.	Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by Network, October–December 2003. 2004 ESRD CPM Project.	35
36.	Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by selected patient characteristics and clinical parameters, October-December 2003. 2004 ESRD CPM Project.	36
37.	Distribution of mean intravenous iron doses (mg/month) for adult in-center hemodialysis patients, October-December 2003. 2004 ESRD CPM Project.	36
38.	Percent of adult in-center hemodialysis patients with mean hemoglobin values ≥ 11 g/dL, by race, October–December 2003 compared to previous study periods. 2004 ESRD CPM Project.	38
39.	Mean prescribed weekly Epoetin dose (units/kg/week) for adult in-center hemodialysis patients, by hemoglobin category and route of administration, October–December 2003 compared to selected previous study periods. 2004 ESRD CPM Project.	38
40.	Percent of adult in-center hemodialysis patients with specific anemia management indicators, October–December 2003 compared to selected previous study periods. 2004 ESRD CPM Project.	38
41.	Distribution of mean serum albumin for adult in-center hemodialysis patients, by laboratory method, October–December 2003. 2004 ESRD CPM Project.	39
42.	Percent of adult in-center hemodialysis patients with mean serum albumin $\geq$ 4.0/3.7 g/dL (BCG/BCP) and $\geq$ 3.5/3.2 g/dL (BCG/BCP), by race and gender, October–December 2003. 2004 ESRD CPM Project.	40
43.	Percent of adult in-center hemodialysis patients with mean serum albumin $\geq$ 4.0/3.7 g/dL (BCG/BCP) and $\geq$ 3.5/3.2 g/dL (BCG/BCP), by age, October–December 2003. 2004 ESRD CPM Project.	40
44.	Percent of adult in-center hemodialysis patients with mean serum albumin $\geq$ 4.0/3.7 g/dL (BCG/BCP) and $\geq$ 3.5/3.2 g/dL (BCG/BCP), October–December 2003 compared to selected previous study periods. 2004 ESRD CPM Project.	40

Fiç	gure Title	Page
45.	Distribution of Peritoneal Equilibration Test (PET) results for adult peritoneal dialysis patients, October 2003-March 2004. 2004 ESRD CPM Project.	43
46.	Distribution of single dwell volumes for adult CAPD patients, October 2003-March 2004. 2004 ESRD CPM Project.	43
47.	Distribution of 24-hour total infused dialysate volumes for adult CAPD patients, October 2003-March 2004. 2004 ESRD CPM Project.	43
48.	Distribution of mean single nighttime dwell volumes for all adult cycler patients, October 2003-March 2004. 2004 ESRD CPM Project.	45
49.	Distribution of the mean number of nighttime exchanges for all adult cycler patients, October 2003-March 2004. 2004 ESRD CPM Project.	45
50.	Distribution of mean single daytime dwell volumes for adult cycler patients with a daytime dwell, October 2003-March 2004. 2004 ESRD CPM Project.	45
51.	Distribution of the mean number of daytime exchanges for adult cycler patients with a daytime dwell, October 2003-March 2004. 2004 ESRD CPM Project.	45
52.	Percent of adult peritoneal dialysis patients meeting 1997 NKF-DOQI guidelines for weekly $\rm Kt/V_{urea}$ and weekly creatinine clearance (PD Adequacy CPM III). 2003 ESRD CPM Project.	45
53.	Distribution of mean hemoglobin values for adult peritoneal dialysis patients in the US, by race, October 2003–March 2004. 2004 ESRD CPM Project.	46
54.	Percent of adult peritoneal dialysis patients with mean hemoglobin ≥ 11 g/dL, by race, October 2003–March 2004 compared to previous study periods. 2004 ESRD CPM Project.	48
55.	Mean weekly Epoetin dose (units/kg/week) by hemoglobin category for adult peritoneal dialysis patients prescribed Epoetin, October 2003-March 2004 compared to previous study periods. 2004 ESRD CPM Project.	48
56.	Percent of adult peritoneal dialysis patients with specific anemia management indicators, October 2003-March 2004 compared to selected previous study periods. 2004 ESRD CPM Project.	48
57.	Percent of adult peritoneal dialysis patients with mean serum albumin $\geq$ 4.0/3.7 g/dL (BCG/BCP) and $\geq$ 3.5/3.2 g/dL (BCG/BCP), October 2003–March 2004 compared to previous study periods. 2004 ESRD CPM Project.	49
58.	Distribution of mean delivered calculated, single session spKt/V values for all pediatric (aged <18 years) in-center hemodialysis patients, by age group, October-December 2003. 2004 ESRD CPM Project.	50
59.	Percent of all pediatric (aged 0 to < 12 years) male in-center hemodialysis patients with mean delivered calculated, single session spKt/V $\geq$ 1.2, by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	51
60.	Percent of all pediatric (aged 0 to < 12 years) female in-center hemodialysis patients with mean delivered calculated, single session spKt/V $\geq$ 1.2, by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	51
61.	Percent of all pediatric (aged 12 to < 18 years) male in-center hemodialysis patients with mean delivered calculated, single session spKt/V $\geq$ 1.2, by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	52
62.	Percent of all pediatric (aged 12 to < 18 years) female in-center hemodialysis patients with mean delivered calculated, single session $spKt/V \ge 1.2$ , by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	52

Fiç	gure Title	Page
63.	Distribution of mean delivered blood pump flow rates normalized for BSA 60 minutes into the dialysis session for all pediatric (aged < 18 years) in-center hemodialysis patients by access type, October-December 2003. 2004 ESRD CPM Project.	53
64.	Vascular access type for pediatric (aged 0 to < 12 years) in-center hemodialysis patients on their last hemodialysis session during the study period, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	53
65.	Vascular access type for pediatric (aged 12 to < 18 years) in-center hemodialysis patients on their last hemodialysis session during the study period, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	54
66.	Distribution of mean hemoglobin values (g/dL) for all pediatric (aged < 18 years) in-center hemodialysis patients, by race, October-December 2003. 2004 ESRD CPM Project.	54
67.	Percent of all pediatric (aged < 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by selected patient characteristics and clinical parameters, October-December 2003. 2004 ESRD CPM Project.	55
68.	Percent of pediatric (aged 0 to < 12 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by gender, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	56
69.	Percent of pediatric (aged 0 to < 12 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	56
70.	Percent of pediatric (aged 0 to < 12 years) in-center hemodialysis patients with specific anemia management indicators, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	56
71.	Percent of pediatric (aged 12 to < 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by gender, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	56
72.	Percent of pediatric (aged 12 to < 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	57
73.	Mean prescribed weekly IV Epoetin dose (units/kg/week) for pediatric (aged 12 to < 18 years) in-center hemodialysis patients, by hemoglobin category, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	57
74.	Iron management parameters for pediatric (aged 12 to < 18 years) in-center hemodialysis patients, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	57
75.	Percent of pediatric (aged < 18 years) in-center hemodialysis patients with mean serum albumin $\geq$ 4.0/3.7 g/dL (BCG/BCP) and $\geq$ 3.5/3.2 g/dL (BCG/BCP), by age, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	58
76.	Percent of pediatric (aged 0 to < 12 years) in-center hemodialysis patients with mean serum albumin $\geq$ 4.0/3.7 g/dL (BCG/BCP) and $\geq$ 3.5/3.2 g/dL (BCG/BCP), October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	58
77.	Percent of pediatric (aged 12 to < 18 years) in-center hemodialysis patients with mean serum albumin $\geq$ 4.0/3.7 g/dL (BCG/BCP) and $\geq$ 3.5/3.2 g/dL (BCG/BCP), October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.	58

#### X. Appendices

#### Appendix 1. ESRD Clinical Performance Measures (CPMs) for 2004 Data Collection Effort

Study period for HD patients is Oct, Nov, Dec 2003; for PD patients is Oct, Nov, Dec 2003 and Jan, Feb, Mar 2004

#### Hemodialysis (HD) Adequacy

#### 1. HD Adequacy CPM I: Monthly Measurement of Delivered Hemodialysis Dose.

HD Adequacy Guideline 1: Regular Measurement of the Delivered Dose of Hemodialysis (Evidence).

The dialysis care team should routinely measure and monitor the delivered dose of hemodialysis.

HD Adequacy Guideline 6: Frequency of Measurement of Hemodialysis Adequacy (Opinion).

The delivered dose of hemodialysis should be measured at least once a month in all adult and pediatric hemodialysis patients. The frequency of measurement of the delivered dose of hemodialysis should be increased when:

- 1. Patients are noncompliant with their hemodialysis prescriptions (missed treatments, late for treatments, early sign-off from hemodialysis treatments, etc.).
- 2. Frequent problems are noted in delivery of the prescribed dose of hemodialysis (such as variably poor blood flows, or treatment interruptions because of hypotension or angina pectoris).
- 3. Wide variability in urea kinetic modeling results is observed in the absence of prescription changes.
- 4. The hemodialysis prescription is modified.

#### **Numerator:**

Number of patients in denominator with documented monthly adequacy measurements (URR or spKt/V) during the study period. (The study period for HD patients is Oct, Nov, Dec 2003).

#### **Denominator:**

All adult (≥ 18 years old) HD patients in the sample for analysis.

#### 2. HD Adequacy CPM II: Method of Measurement of Delivered Hemodialysis Dose.

HD Adequacy Guideline 2: Method of Measurement of Delivered Dose of Hemodialysis (Evidence).

The delivered dose of hemodialysis in adult and pediatric patients should be measured using formal urea kinetic modeling (UKM), employing the single-pool, variable volume model.

#### **Numerator:**

Number of patients in denominator for whom delivered HD dose was calculated using formal urea kinetic modeling or Daugirdas II during the study period.

#### **Denominator:**

All adult (≥ 18 years old) HD patients in the sample for analysis.

#### 3. HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose.

HD Adequacy Guideline 4: Minimum Delivered Dose of Hemodialysis (Adults-Evidence, Children-Opinion). The dialysis care team should deliver a spKt/V of at least 1.2 (single-pool, variable volume) for both adult and pediatric hemodialysis patients. For those using the urea reduction ratio (URR), the delivered dose should be equivalent to a spKt/V of 1.2, i.e., an average URR of 65%; however URR can vary substantially as a function of fluid removal.

#### **Numerator:**

Number of patients in denominator whose average delivered dose of HD (calculated from data points on the data collection form) was a sp $Kt/V \ge 1.2$  during the study period.

#### Denominator:

All adult (≥18 years old) HD patients in the sample for analysis who have been on HD for six months or more and dialyzing three times per week.

#### Peritoneal Dialysis (PD) Adequacy

#### 4. PD Adequacy CPM I: Measurement of Total Solute Clearance at Regular Intervals.

PD Adequacy Guideline 4: Measures of Peritoneal Dialysis Dose and Total Solute Clearance (Opinion).

Both total weekly creatinine clearance normalized to 1.73 m² body surface area (BSA) and total weekly Kt/V<sub>urea</sub> should be used to measure delivered peritoneal dialysis doses.

PD Adequacy Guideline 11: Dialysate and Urine Collections (Opinion).

Two to three total solute removal measurements are required during the first six months of peritoneal dialysis (See Guideline 3). After six months, if the dialysis prescription is unchanged:

1. Perform both complete dialysate and urine collections every four months; and

2. Perform urine collections every two months until the renal weekly Kt/V<sub>urea</sub> is <0.1.

Thereafter, urine collections are no longer necessary, as the residual renal function contribution to total Kt/V<sub>urea</sub> becomes negligible (See Guideline 5).

#### **Numerator:**

Number of patients in denominator with total solute clearance for urea and creatinine measured at least once in a 6 month time period. (The study period for PD patients is Oct, Nov, Dec 2003 and Jan, Feb, Mar 2004).

#### **Denominator:**

All adult (≥ 18 years old) PD patients in sample for analysis, excluding tidal dialysis patients.

#### 5. PD Adequacy CPM II: Calculate Weekly Kt/V<sub>urea</sub> and Creatinine Clearance in a Standard Way.

PD Adequacy Guideline 4: Measures of Peritoneal Dialysis Dose and Total Solute Clearance (Opinion).

Both total weekly creatinine clearance normalized to 1.73 m<sup>2</sup> body surface area (BSA) and total weekly Kt/V<sub>urea</sub> should be used to measure delivered peritoneal dialysis doses.

PD Adequacy Guideline 6: Assessing Residual Renal Function (Evidence).

Residual renal function (RRF), which can provide a significant component of total solute and water removal, should be assessed by measuring the renal component of Kt/V<sub>urea</sub> and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance.

PD Adequacy Guideline 9: Estimating Total Body Water and Body Surface Area (Opinion).

V (total body water) should be estimated by either the Watson or Hume method in adults using actual body weight.

Watson method:

For Men: V (liters) = 2.447 + 0.3362\*Wt(kg) + 0.1074\*Ht(cm) - 0.09516\*Age(years)

For Women: V = -2.097 + 0.2466\*Wt + 0.1069\*Ht

Hume method:

For Men: V = -14.012934 + 0.296785\*Wt + 0.192786\*HtFor Women: V = -35.270121 + 0.183809\*Wt + 0.344547\*Ht

BSA should be estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method using actual body weight.

For all formulae, Wt is in kg and Ht is in cm:

DuBois and DuBois method: BSA ( $m^2$ ) = 0.007184\*Wt<sup>0.425\*</sup>Ht<sup>0.725</sup> Gehan and George method: BSA ( $m^2$ ) = 0.0235\*Wt<sup>0.51456\*</sup>Ht<sup>0.42246</sup>

Haycock method: BSA ( $m^2$ ) = 0.024265\*Wt<sup>0.5378</sup>\*Ht<sup>0.3964</sup>

#### **Numerator:**

The number of patients in denominator with all of the following:

- a. Weekly creatinine clearance normalized to 1.73 m² body surface area (BSA) and total weekly Kt/V<sub>urea</sub> used to measure delivered PD dose; and
- b. Residual renal function (unless negligible\*) is assessed by measuring the renal component of  $Kt/V_{urea}$  and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance; and
- c. Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method of using actual body weight, during the study period.
- \* negligible = < 200 mL urine in 24 hours.

#### **Denominator:**

All adult (≥ 18 years old) PD patients in the sample for analysis, excluding tidal dialysis patients.

#### 6. PD Adequacy CPM III: Delivered Dose of Peritoneal Dialysis.

PD Adequacy Guideline 15: Weekly Dose of CAPD (Evidence).

For CAPD, the delivered peritoneal dialysis dose should be a total Kt/V<sub>urea</sub> of at least 2.0 per week and a total creatinine clearance (CrCl) of at least 60 L/week/1.73 m<sup>2</sup>.

PD Adequacy Guideline 16: Weekly Dose of NIPD and CCPD (Opinion).

For NIPD, the weekly delivered peritoneal dialysis dose should be a total  $Kt/V_{urea}$  of at least 2.2 and a weekly total CrCL of at least 66 L/1.73 m<sup>2</sup>.

For CCPD, the weekly delivered peritoneal dialysis dose should be a total Kt/V<sub>urea</sub> of at least 2.1 and a weekly total CrCl of at least 63 L/1.73 m<sup>2</sup>.

#### Numerator:

a. For CAPD patients in the denominator, the delivered PD dose was a weekly  $Kt/V_{urea}$  of at least 2.0 and a weekly CrCl of at least 60 L/week/1.73 m<sup>2</sup> or evidence that the prescription was changed according to NKF-K/DOQI recommendations, during the study period.

b. For cycler patients in the denominator without a daytime dwell (NIPD), the delivered PD dose was a weekly Kt/V $_{urea}$  of at least 2.2 and a weekly CrCl of at least 66 L/week/1.73 m $^2$  or evidence that the prescription was changed according to NKF-K/DOQI recommendations, during the study period. For cycler patients in the denominator with a daytime dwell (CCPD), the delivered PD dose was a weekly Kt/V $_{urea}$  of at least 2.1 and a weekly CrCl of at least 63 L/week/1.73 m $^2$  or evidence that the prescription was changed according to NKF-K/DOQI recommendations, during the study period.

#### **Denominator:**

All adult (≥ 18 years old) PD patients in the sample for analysis, excluding tidal dialysis patients.

#### Vascular Access

#### 7. Vascular Access CPM I: Maximizing Placement of Arterial Venous Fistulae (AVF).

Vascular Access Guideline 29A: Goals of Access Placement-Maximizing Primary Arterial Venous Fistulae (Opinion). Primary arterial venous fistulae (AVF) should be constructed in at least 50% of all new patients electing to receive hemodialysis as their initial form of renal replacement therapy. Ultimately, 40% of prevalent patients should have a native AV fistula. (See Guideline 3, Selection of Permanent Vascular Access and Order of Preference of AV Fistulae).

#### Numerator:

- a. The number of incident patients in the denominator who were dialyzed using an AVF during their last HD treatment during the study period. (The study period for HD patients is Oct, Nov, Dec 2003).
- b. The number of prevalent patients in the denominator who were dialyzed using an AVF during their last HD treatment during the study period.

#### **Denominator:**

- a. Incident adult (≥ 18 years old) HD patients (defined as those patients initiating their most recent course of HD on or between Jan 1 and Aug 31,2002) in the sample for analysis.
- b. Prevalent adult (> 18 years old) HD patients in the sample for analysis.

#### 8. Vascular Access CPM II: Minimizing Use of Catheters as Chronic Dialysis Access.

Vascular Access Guideline 30A: Goals of Access Placement- Use of Catheters for Chronic Dialysis (Opinion). Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters as their permanent chronic dialysis access. In this context, chronic catheter access is defined as the use of a dialysis catheter for more than three months in the absence of a maturing permanent access.

#### Numerator

The number of patients in the denominator who were dialyzed with a chronic catheter continuously for 90 days or longer prior to the last HD session during the study period.

#### Denominator:

All adult (≥ 18 years old) patients in the sample for analysis.

#### 9. Vascular Access CPM III: Monitoring Arterial Venous Grafts for Stenosis

Vascular Access Guideline 10: Monitoring Dialysis AV Grafts for Stenosis (Evidence/Opinion).

Physical examination of an access graft should be performed weekly and should include, but not be limited to, inspection and palpation for pulse and thrill at the arterial, mid, and venous sections of the graft (Opinion). Dialysis arterial venous graft accesses should be monitored for hemodynamically significant stenosis. The DOQI Work Group recommends an organized monitoring approach with regular assessment of clinical parameters of the arterial venous access and dialysis adequacy. Data from the monitoring tests, clinical assessment, and dialysis adequacy measurements should be collected and maintained for each patient's access and made available to all staff. The data should be tabulated and tracked within each dialysis center as part of a Quality Assurance/Continuous Quality Improvement (QA/CQI) program (Opinion). Prospective monitoring of arterial venous grafts for hemodynamically significant stenosis, when combined with correction, improves patency and decreases the incidence of thrombosis (Evidence). Techniques, not mutually exclusive, that can be used to monitor for stenosis in arterial venous grafts include:

A. Intra-access flow (Evidence)

- B. Static venous pressures (Evidence)
- C. Dynamic venous pressures (Evidence)

Other studies or information that can be useful in detecting arterial venous graft stenosis include:

- D. Measurement of access recirculation using urea concentrations (See Guideline 12) (Evidence)
- E. Measurement of recirculation using dilution flow techniques (nonurea-based) (Evidence)
- F. Unexplained decreases in the measured amount of hemodialysis delivered (URR, Kt/V) (Evidence)
- G. Physical findings of persistent swelling of the arm, clotting of the graft, prolonged bleeding after needle withdrawal, or altered characteristics of pulse or thrill in a graft (Evidence/Opinion)
- H. Elevated negative arterial pre-pump pressures that prevent increasing to acceptable blood flow (Evidence/Opinion)
- I. Doppler ultrasound (Evidence/Opinion)

Persistent abnormalities in any of these parameters should prompt referral for venography (Evidence).

#### **Numerator:**

The number of patients in the denominator whose AV graft was routinely monitored (screened) for the presence of stenosis during the study period by one of the following methods and with the stated frequency: Color-flow Doppler at least once every 3 months; Static venous pressure at least once every 2 weeks; Dynamic venous pressure every HD session; Dilution technique at least once every 3 months.

#### **Denominator:**

All adult (≥ 18 years old) patients in the sample for analysis who were on HD continuously during the study period and who were dialyzed through an arterial venous graft during their last HD session during the study period.

#### **Anemia Management**

#### 10. Anemia Management CPM I: Target Hemoglobin for Epoetin Therapy.

Anemia Management Guideline 4: Target Hemoglobin (Hgb) for Epoetin Therapy (Evidence/Opinion).

The target range for hemoglobin should be 11-12 g/dL (110-120 g/L) (Evidence). This target is for Epoetin therapy and is not an indication for blood transfusion therapy (Opinion).

#### **Numerator:**

Number of patients in denominator with documented mean Hgb of 11-12 g/dL (110-120 g/L) during the study period. (The study period for HD patients is Oct, Nov, Dec 2002 and Oct, Nov, Dec 2003 and Jan, Feb, Mar 2004 for PD patients).

#### **Denominator:**

All adult (≥ 18 years old) HD or PD patients in the sample for analysis, exclude patients with mean Hgb > 12 g/dL (120 g/L) who are not prescribed Epoetin at any time during the study period.

## 11. Anemia Management CPM IIa: Assessment of Iron Stores among Anemic Patients or Patients Prescribed Epoetin.

Anemia Management Guideline 5: Assessment of Iron Status (Evidence).

Iron status should be monitored by the percent transferrin saturation and the serum ferritin concentration.

Anemia Management Guideline 6A: Target Iron Level (Evidence).

Chronic renal failure patients should have sufficient iron to achieve and maintain a Hgb of 11 to 12 g/dL (110-120 g/L).

Anemia Management Guideline 7A: Monitoring Iron Status (Opinion).

During the initiation of Epoetin therapy and while increasing the Epoetin dose in order to achieve an increase in hematocrit/hemoglobin, the transferrin saturation and the serum ferritin concentration should be checked every month in patients not receiving intravenous iron, and at least once every 3 months in patients receiving intravenous iron, until target hematocrit/hemoglobin is reached.

Anemia Management Guideline 7B: Monitoring Iron Status (Opinion).

Following attainment of the target hematocrit/hemoglobin, transferrin saturation and serum ferritin concentration should be determined at least once every 3 months.

#### **Numerator:**

- a. The number of HD patients in the denominator with at least one documented transferrin saturation and serum ferritin concentration result every three months.
- b. The number of PD patients in the denominator with at least two documented transferrin saturation and serum ferritin concentration results over the six-month study period.

[Note: Not directly comparable to Numerator "a", but most feasible given probable frequency of visits for PD patients.]

#### **Denominator:**

- a. All adult ( $\geq$  18 years old) HD patients included in the sample for analysis, if first monthly Hgb is < 11 g/dL (110 g/L) for at least one of the study months or if prescribed Epoetin at any time during the study period regardless of Hgb.
- b. All adult (≥ 18 years old) PD patients included in the sample for analysis, if first monthly Hgb is < 11 g/dL (110 g/L) for at least one of the two-month periods during the six-month study period or if prescribed Epoetin at any time during the study period regardless of Hgb.

#### 12. Anemia Management CPM IIb: Maintenance of Iron Stores-Target.

Anemia Management Guideline 6B: Target Iron Level (Evidence).

To achieve and maintain target Hgb of 11-12 g/dL (110-120 g/L), sufficient iron should be administered to maintain a transferrin saturation of  $\geq$  20%, and a serum ferritin concentration of >100 ng/mL.

#### **Numerator:**

a. The number of HD patients in the denominator with at least one documented transferrin saturation  $\geq$  20% and at least one documented serum ferritin concentration  $\geq$  100 ng/mL during a three-month period.

b. The number of PD patients in the denominator with at least one documented transferrin saturation  $\geq$  20% and at least one documented serum ferritin concentration  $\geq$  100 ng/mL during the six-month study period.

[Note: Not directly comparable to Numerator "a", but most feasible given probable frequency of visits for PD patients.]

#### **Denominator:**

- a. All adult (≥ 18 years old) HD patients included in sample, if first monthly Hgb is < 11 g/dL (110 g/L) for at least one of the study months or if prescribed Epoetin at any time during the study period regardless of Hgb.
- b. All adult ( $\geq$  18 years old) PD patients included in sample, if first monthly Hgb is < 11 g/dL (110 g/L) for at least one of the two-month periods during the six-month study period or if prescribed Epoetin at any time during the study period regardless of Hgb.

#### 13. Anemia management CPM III: Administration of Supplemental Iron.

Anemia Management Guideline 8A: Administration of Supplemental Iron (Evidence).

Supplemental iron should be administered to prevent iron deficiency and to maintain adequate iron stores so that chronic renal failure patients can achieve and maintain a Hgb of 11 to 12 g/dL (110-120 g/L) in conjunction with Epoetin therapy.

Anemia Management Guideline 8C: Administration of Supplemental Iron (Evidence/Opinion).

The adult pre-dialysis, home hemodialysis, and peritoneal dialysis patient may not be able to maintain adequate iron status with oral iron. Therefore, 500 to 1000 mg of iron dextran may be administered intravenously in a single infusion, and repeated as needed, after an initial one-time test dose of 25 mg.

Anemia Management Guideline 8D: Administration of Supplemental Iron (Opinion/Evidence).

A trial of oral iron is acceptable in the hemodialysis patient, but is unlikely to maintain the transferrin saturation > 20%, serum ferritin concentration > 100 ng/mL, and Hgb at 11-12 g/dL (110-120 g/L).

Anemia Management Guideline 8G: Administration of Supplemental Iron (Opinion/Evidence).

Most patients will achieve a Hgb 11 to 12 g/dL (110-120 g/L) with transferrin saturation and serum ferritin concentration < 50% and < 800 ng/mL, respectively. In patients in whom transferrin saturation is 50% and/or serum ferritin concentration is 800 ng/mL, intravenous iron should be withheld for up to three months, at which time the iron parameters should be re-measured before intravenous iron is resumed. When the transferrin saturation and serum ferritin concentration have fallen to 50% and 800 ng/mL, respectively, intravenous iron can be resumed at a dose reduced by one-third to one-half.

Anemia Management Guideline 8H: Administration of Supplemental Iron (Opinion).

It is anticipated that once optimal hematocrit/hemoglobin and iron stores are achieved, the required maintenance dose of intravenous iron may vary from 25 to 100 mg/week for hemodialysis patients. The goal is to provide a weekly dose of intravenous iron in hemodialysis patients that will allow the patient to maintain the target hematocrit/hemoglobin at a safe and stable iron level. The maintenance iron status should be monitored by measuring the transferrin saturation and serum ferritin concentration every three months.

#### **Numerator:**

- a. The number of HD patients in the denominator prescribed intravenous iron in at least one of the study months.
- b. The number of PD patients in denominator prescribed intravenous iron in at least one of the two-month periods during the six-month study period

#### **Denominator:**

- a. All adult ( $\geq$  18 years old) HD patients included in the sample for analysis if first monthly Hgb < 11 g/dL (110 g/L) for at least one month out of a three-month period or prescribed Epoetin at any time during the study period regardless of Hgb level, with at least one transferrin saturation < 20% or at least one serum ferritin concentration < 100 ng/mL. EXCLUDE patients with mean transferrin saturation  $\geq$  50% or mean serum ferritin concentration  $\geq$  800 ng/mL and EXCLUDE patients in first three months of dialysis and prescribed oral iron.
- b. All adult ( $\geq$  18 years old) PD patients included in the sample for analysis if the first Hgb in a two-month period < 11 g/dL (110 g/L) for at least one of the two-month periods during the six-month study period or prescribed Epoetin at any time during the study period regardless of Hgb level, with at least one transferrin saturation < 20% or at least one serum ferritin concentration < 100 ng/mL. EXCLUDE patients with mean transferrin saturation  $\geq$  50% or mean serum ferritin concentration  $\geq$  800 ng/mL and EXCLUDE patients in first three months of dialysis and prescribed oral iron.

#### Appendix 2. 2004 CPM Data Collection Form – In-Center Hemodialysis

# IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004

[Before completing please read instructions at the bottom of this page and on pages 4, 5 and 6]

PATIENT IDENTIFICATION	MAKE CORRECTIONS TO PATIENT INFORMATION ON LABEL IN THE SPACE BELOW	
Place Patient Data Label Here		
$12. \  $ If this patient is unknown or was not dialyzed in the facility at form to the Network.	any time during OCT 2003-DEC 2003 return the blank	
13. Patient's Ethnicity (Check appropriate box). ☐ non-Hispanic ☐ Hispanic, Mexican American (Chicano) ☐ Hispanic, Puerto Rican ☐ Hispanic, Cuban American ☐ Hispanic, Other ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐		
14. Patient's height (MUST COMPLETE):inches ORcentimeters (only for patients < 18 years old, provide date when height was measured:/ // (mm) / (dd) / (yyyy)		
15. Did patient have limb amputation(s) prior to Dec. 31, 2003: ☐ Yes ☐ No ☐ Unknown		
16. Has the patient ever been diagnosed with any type of diabetes?	☐ Yes (go to 17) ☐ No (go to 18) ☐ Unknown (go to 18)	
17. If question 16 was answered <b>YES</b> , was the patient taking medications to control the diabetes during the study period?  \[ \textstyle \text		
Individual Completing Form (Please print):		
First name: Last name:	Title:	
Phone number: () Fax number	r: (	

#### INSTRUCTIONS FOR COMPLETING THE IN-CENTER HEMODIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004

The label on the top left side of this form contains the following patient identifying information (#'s 1-11). If the information is incorrect make corrections to the right of the label.

- 1. LAST and first name.
- 3. SOCIAL Security Number (SSN).
- 5. GENDER (1=Male; 2=Female).
- 7. PRIMARY cause of renal failure by CMS-2728 code.
- ESRD Network number.Do not make corrections to this item.
- 2. DATE of birth (DOB) as MM/DD/YYYY.
- 4. HEALTH Insurance Claim Number (HIC), (same as Medicare number).
- 6. RACE (1=American Indian/Alaska Native; 2=Asian; 3=Black; 4=White; 5=Unknown; 6=Pacific Islander; 7=Mid East Arabian; 8=Indian Subcontinent; 9=Other Multiracial).
- 8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.
- 10. Facility's Medicare provider number.
- 11. The most RECENT date this patient returned to hemodialysis following: transplant failure, an episode of regained kidney function, or switched modality.
- 12. If the patient is unknown or if the patient was not dialyzed in the facility at any time during OCT 2003 through DEC 2003, send the blank form back to the ESRD Network office. Provide the name and address of the facility providing services to this patient on December 31, 2003, if known.
- 13. Patient's Ethnicity. Please verify the patient's ethnicity with the patient and check appropriate box.
- 14. Enter the patient's height in inches or centimeters. HEIGHT MUST BE ENTERED, do not leave this field blank. You may ask the patient his/her height to obtain this information. If the patient had both legs amputated, record pre-amputation height and check YES for item 15.
- 15. For the purpose of this study, check NO if this patient has had toe(s), finger(s), or mid-foot (Symes) amputation; but check YES if this patient has had a below-knee, below-elbow, or more proximal (extensive) amputation prior to Dec. 31, 2003.
- 16. Check either "Yes", "No", or "Unknown" to indicate if the patient has ever been diagnosed with any type of diabetes. If **YES**, proceed to question 17.
- 17. Check either "Yes", "No", or "Unknown" to indicate if the patient was taking medications to control the diabetes during the study period. If the answer to 17 is **YES**, please check either "Yes", "No", or "Unknown" to indicate if the patient was using insulin during the study period. Study period is OCT 2003-DEC 2003.

18. ANEMIA MANAGEMENT: For each lab question below, enter the lab value obtained from the monthly lab draw for each month: OCT, NOV, DEC 2003. Enter NF/NP if the lab value cannot be located.

	OCT 2003	NOV 2003	<b>DEC 2003</b>
A. Pre-dialysis laboratory hemoglobin (Hgb) from the monthly lab draw:	g/dL (If NF/NP go to 18C)	g/dL (If NF/NP go to 18C)	g/dL (If NF/NP go to 18C)
B.1.a. Did the patient receive Epoetin at any time during the 30 days before the Hgb in 18A was drawn?	Epoetin:  Yes No Unknown	Epoetin:  Yes No Unknown	Epoetin:  Yes No Unknown
B.1.b. Did the patient receive Darbepoetin (Aranesp <sup>TM</sup> ) at any time during the 30 days before the Hgb in 18A was drawn?	Darbepoetin: ☐ Yes ☐ No ☐ Unknown	Darbepoetin: ☐ Yes ☐ No ☐ Unknown	Darbepoetin: ☐ Yes ☐ No ☐ Unknown
B.2.a. What was the PRESCRIBED Epoetin dose in units for each treatment during the 7 days immediately BEFORE the Hgb in 18A was drawn? (See instructions on page 4)	Epoetin:units/txunits/txunits/tx	Epoetin:units/txunits/txunits/tx	Epoetin:units/txunits/txunits/tx
B.2.b. What was the PRESCRIBED Darbepoetin dose in micrograms for the MONTH immediately BEFORE the Hgb in 18A was drawn? (See instructions on page 4)	Darbepoetin: mcg/month	Darbepoetin: mcg/month	Darbepoetin: mcg/month
B.3. a. How many times per week was Epoetin prescribed? Check box if prescribed < 1 x per week.	Epoetin: x per week < 1 x per week	Epoetin: $x \text{ per week}$ $< 1 \text{ x per week}$	Epoetin: $x \text{ per week}$ $< 1 \text{ x per week}$
B.3.b. How many times per month was Darbepoetin prescribed?	Darbepoetin:x per month	Darbepoetin:x per month	Darbepoetin:x per month
B.4. a. What was the prescribed route of administration for Epoetin? (Check all that apply)	Epoetin:  □IV □SC □ Unknown	Epoetin:  IV ISC Unknown	Epoetin: ☐ IV ☐ SC ☐ Unknown
B.4.b. What was the prescribed route of administration for Darbepoetin? (Check all that apply)	Darbepoetin: ☐ IV ☐ SC ☐ Unknown	Darbepoetin: ☐ IV ☐ SC ☐Unknown	Darbepoetin: ☐ IV ☐ SC ☐ Unknown
C. Serum ferritin concentration from the monthly lab draw:	ng/mL	ng/mL	ng/mL
D. % transferrin (iron) saturation from the monthly lab draw:	%	%	%
E. Was iron prescribed at any time during the month?	☐ Yes ☐ No (go to 19) ☐ Unknown (go to 19)	☐ Yes ☐ No (go to 19) ☐ Unknown (go to 19)	☐ Yes ☐ No (go to 19) ☐ Unknown (go to 19)
F. If yes, what was the prescribed route of iron administration? (Check all that apply).	□ IV □ PO □ Unknown	□ IV □ PO □ Unknown	□ IV □ PO □ Unknown
G. If the patient was prescribed IV iron, what was the total dose of IV iron <b>administered</b> during the month?	mg/month	mg/month	mg/month

19. SERUM ALBUMIN: Enter the serum albumin obtained from the monthly lab draw for each month: OCT, NOV and DEC
2003. Enter NF/NP if the lab value cannot be located. Check the method used (BCG/bromcresol green or BCP/bromcresol purple)
by the lab to determine serum albumin. If lab method unknown, please call lab to find out.

		OCT 2003	NOV 2003	DEC 2003
A.	Serum albumin from the monthly lab draw:	g/dL	g/dL	g/dL
В.	Check lab method used: BCG = bromcresol green; BCP = bromcresol purple	□ BCG □ BCP	□ BCG □ BCP	□ BCG □ BCP
	ADEQUACY: Enter the information requested neasure adequacy for each month: OCT, NOV,			
		OCT 2003	NOV 2003	DEC 2003
A.	How many times per week was this patient prescribed to receive dialysis?	times per week	times per week	times per week
В.	Recorded URR from the monthly lab draw:	%	%	%
C.	Recorded single-pool Kt/V from the monthly lab draw:	·	·-	·-
D.	Method used to calculate the single-pool Kt/V in 20C: (If unknown, please ask Medical Director)	☐ UKM ☐ Daugirdas II ☐ Depner ☐ Derived from URR based on no pt. wts. ☐ Other	□ UKM □ Daugirdas II □ Depner □ Derived from URR based on no pt. wts. □ Other	□ UKM □ Daugirdas II □ Depner □ Derived from URR based on no pt. wts. □ Other
E.	Was residual renal function used to calculate the single-pool Kt/V in 20C on this patient?	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐Unknown
F.	Pre-dialysis BUN value from the monthly lab draw:	mg/dL	mg/dL	mg/dL
G.	Post-dialysis BUN value from the monthly lab draw: (both the pre & post dialysis BUN must be drawn on the same day)	mg/dL	mg/dL	mg/dL
Н.	Pre- & Post-dialysis weight at session when BUNs above drawn: (Circle either lbs or kgs)		Pre: lbs/kgs Post: lbs/kgs	
I.	Actual DELIVERED time on dialysis at session when BUNs above drawn:	hrs min	hrs min	hrs min
J.	Delivered blood pump flow rate @ 60 minutes after start of dialysis session when BUNs above drawn:	mL/min	mL/min	mL/min
K.	Code for dialyzer used for dialysis session when BUNs above drawn: (see chart)			

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)			
21. VASCULAR ACCESS: What type of access was used on the last hemodialysis session on or between 10/1/2003 and 12/31/2003 at the patient's primary in-center facility? Check only one of the following access types and follow the corresponding directions.			
☐ AV Fistula☐ Synthetic Graft	Was routine surveillance for the presence of ster     Yes □ No □ Unknown	nosis performed between 10/1/03 and 12/31/03?	
☐ Bovine Graft  If you checked AV Fistula or Synthetic or Bovine Graft, please answer questions 1 and 2 at the right.	2. If answer to question 1 is "Yes," please check a (See instructions on page 6).  ☐ Color-Flow Doppler at least once between 10/☐ Static Venous Pressure at least once every 2 w ☐ Dynamic Venous Pressure every HD session b ☐ Dilution Technique at least once between 10/1☐ Other	eeks between 10/1/03 and 12/31/03 etween 10/1/03 and 12/31/03	
☐ Catheter ☐ Port Access  If you checked Catheter or Port Access, please answer questions 1 and 2 at the right.	<ol> <li>Reason for catheter or port access:</li> <li>☐ Fistula or graft maturing, not ready to cannulate</li> <li>☐ Temporary interruption of fistula or graft due to clotting or revisions</li> <li>☐ All fistula or graft sites have been exhausted</li> <li>☐ No fistula or graft surgically created at this time</li> </ol>	<ul> <li>□ No fistula or graft surgically planned (check all that apply)</li> <li>○ Peripheral vascular disease</li> <li>○ Patient size too small for AV fistula or graft</li> <li>○ Renal transplantation scheduled</li> <li>○ Patient preference</li> <li>○ Physician/Surgeon preference</li> <li>□ Other</li> </ul>	
	2. Had a catheter or port access been used exclusive ☐ Yes ☐ No ☐ Unknown	ly for the past 90 days or longer?	
☐ Unknown			
22. Did the patient FIRST start hemodialysis during January 1, 2003-August 31, 2003 (see date #8 on page 1)? <u>DO NOT</u> include patients who transferred from peritoneal dialysis, had a newly failed transplant, or returned after an episode of regained kidney function (See instructions on page 6).   Yes (answer 22A-B)			
A. What type of access was in use at the <u>Initiation</u> of a maintenance course of hemodialysis (See date #8 on page 1)?  □ AV Fistula □ Synthetic Graft □ Bovine Graft □ Catheter □ Port Access □ Unknown			
* *	B. What type of access was in use 90 days later?  □AV Fistula □Synthetic Graft □ Bovine Graft □Catheter □ Port Access □Unknown		
INSTRUCTIONS FOR COMPLETING QUESTIONS 18 THROUGH 22 (Continued from page 1): To answer questions 18 through 22, review the patient's clinic or facility medical record for OCT 1, 2003 through DEC 31, 2003. Do not leave any items blank. Enter NF/NP if the information cannot be located.			
<b>18A:</b> Enter the patient's pre-dialysis hemoglobin (Hgb) from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If not found or not performed during the month, enter NF/NP.			
<b>18B.1:</b> Check the appropriate box to indicate if the patient received EPOETIN at anytime during the 30 days BEFORE the date of the hemoglobin in 18A or for DARBEPOETIN (Aranesp™) at anytime during the 30 days BEFORE the date of the hemoglobin value in 18A. If the answer is NO to both, skip to question 18C.			
<b>18.B.2:</b> If <b>Epoetin</b> was prescribed, enter the PRESCRIBED Epoetin dose, <b>not the administered dose</b> , in units given at each dialysis treatment during the 7 days immediately before the date of the hemoglobin value in 18A, even if the patient did not receive the dose. This includes any prescribed dose not given because of an error or the patient missed a treatment, etc. Enter "0" if the patient was on "Hold" for a treatment. (For the purposes of this collection, a "Hold" order will be considered a 0 unit prescribed dose.) If Epoetin is prescribed less frequently than every dialysis treatment, leave the unit/tx space blank to indicate one or two doses per the 7-day period.			
micrograms per month dur the dose. This includes any	If <b>Darbepoetin</b> (Aranesp <sup>TM</sup> ) was prescribed, enter the PRESCRIBED MONTHLY Darbepoetin dose, <b>not the administered dose</b> , in micrograms per month during the month immediately before the date of the hemoglobin value in 18A, even if the patient did not receive the dose. This includes any prescribed dose not given because of an error or the patient missed a treatment, etc. Enter "0" if the patient was on "Hold". (For the purposes of this collection, a "Hold" order will be considered a 0 mcg/month prescribed dose.)		
<b>18.B.3:</b> Enter the number of times per week that Epoetin was prescribed (check the box if Epoetin was prescribed less than once per week) OR the number of times per month Darbepoetin was prescribed.			

- **18B.4:** Check the appropriate box to indicate the prescribed route of administration for Epoetin or for Darbepoetin (intravenous [IV] or subcutaneous [SC]). If the patient was prescribed Epoetin or Darbepoetin IV and SC during the month, please check both boxes.
- **18C:** Enter the patient's serum ferritin concentration from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If a serum ferritin concentration test was not found or not performed during the month, enter NF/NP.
- **18D:** Enter the patient's % transferrin (iron) saturation from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If a % transferrin (iron) saturation test was not found or not performed during the month, enter NF/NP.
- **18E:** Check either "Yes", "No", or "Unknown" to indicate if iron was prescribed at any time during the months of OCT, NOV, and DEC 2003. If there was no prescription for iron go to question 19.
- **18F:** If the answer to 18E is "Yes", please check the appropriate box to indicate the route of iron administration (intravenous [IV] or by mouth [PO]) for OCT, NOV, and DEC 2003. If the patient received iron by mouth **and** IV during the month please check both boxes.
- **18G:** If the patient was prescribed IV iron, add together all doses that were given during the month and enter the TOTAL dose of IV iron (in mg) administered per month during OCT, NOV, and DEC 2003.
- **19A**: Enter the patient's serum albumin from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If a serum albumin was not found or not performed during the month, enter NF/NP.
- **19B:** Check the method used by the laboratory to determine the serum albumin value (bromcresol green or bromcresol purple). If you do not know what method the laboratory used, call the lab to find out this information.
- **20A:** Enter the number of times per week the patient was **prescribed** to receive dialysis in OCT, NOV, and DEC 2003. If the prescription varied during a month, enter the prescription in effect the week the monthly labs were drawn. Do not leave this question blank.
- **20B:** Enter the patient's URR recorded on the lab sheet from the monthly lab draw for each month OCT, NOV, DEC 2003. If not found or not performed during a month, enter NF/NP.
- **20C:** Enter the patient's single-pool Kt/V recorded on the lab sheet from the monthly lab draw for each month OCT, NOV, DEC 2003. If not found or not performed during a month, enter NF/NP.
- **20D:** Check the box to indicate the method used to calculate the single-pool Kt/V in 20C. If you do not know what method was used, please ask the unit's Medical Director. Please check the "Other" box if you do not use any of the methods listed. If using another method and you know what it is, please write the method in the space provided.
- **20E:** Check the appropriate box to indicate whether residual renal function was used to calculate the single-pool Kt/V in 20C. If you do not know, please ask the unit's Medical Director.
- **20F & G:** Enter the patient's pre- and post-dialysis BUNs from the monthly lab draw (or the BUNs used to measure adequacy for the month, if there was a blood drawing error when the monthly labs were drawn). Enter NF/NP if not found or not performed during the month.
- **20H:** Enter the patient's pre- and post-dialysis weight at the dialysis session when the pre- and post-dialysis BUNs in question 20F&G were drawn. Circle either lbs or kgs as appropriate.
- **20I:** Enter the patient's total treatment time (actual delivered time) on dialysis during the session when the BUNs in question 20F&G were drawn for months OCT, NOV, DEC 2003. Do not enter the prescribed time on dialysis.
- **20J:** Enter the delivered blood pump flow rate in mL/minutes at 60 minutes after the start of the dialysis session when the BUNs in questions 20F&G were drawn for months OCT, NOV, DEC 2003. Do not enter the prescribed blood pump flow rate or the highest achieved blood pump flow rate.

- 20K: Using the enclosed Dialyzer Code Chart, enter the code for the dialyzer used at the dialysis session when the pre- and post-dialysis BUNs in question 20F&G were drawn for OCT, NOV, DEC 2003. If the dialyzer used is not listed on the chart, enter the code for "other" (9999).
- 21: Check only one type of vascular access used on **last hemodialysis session on or between OCT 1, 2003 and DEC 31, 2003** at the patient's primary in-center facility and then complete the corresponding questions to the right of the access type. Exclude dialysis sessions performed at temporary facilities because of holiday travel or hospitalizations. ("Port Access" is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).

#### AV Fistula, Synthetic Graft, Bovine Graft:

If the vascular access marked for question 21 was an AV fistula, synthetic graft or bovine graft, indicate if routine surveillance for the presence of stenosis between Oct 1, 2003 and Dec 31, 2003 was done. Routine surveillance is the sequential measurement of access flow OR of venous pressure.

- Indicate "YES" for this question if you measure access flow OR venous pressure using any of the following: Techniques and frequencies used to measure access flow include:
  - a. one of the dilution methods in which the needles are reversed and recirculation is deliberately induced on a regular basis, OR
  - b. conventional Color-Flow Doppler at a minimum of once every three months.

Techniques and frequencies used to measure venous pressure include:

a. dynamic venous pressure measured at every hemodialysis session; uses low blood pump flow rates usually set at 200 mL/min.,

OR

- b. static venous pressure measured at a minimum of once every two weeks; performed at zero blood pump flow.
- Indicate" NO" for this question if you only conduct (or note) the following clinical assessments:
  - a. Prolonged bleeding after needle withdrawal.
  - b. Altered characteristics of thrill or bruit.
  - c. Adequacy measurements using Kt/V or URR.
  - d. Recirculation methods.

Continue with question 2 if answered "yes" above and check all surveillance methods utilized based on the definitions and intervals given above. If other techniques and/or corresponding intervals were used check "other" and write in the technique and corresponding intervals.

#### **Catheter or Port Access:**

If the vascular access marked for question 21 was a catheter or port access, indicate in the appropriate space the **reason** for the catheter or port access.

Continue with question 2 and indicate in the appropriate space **if one or more catheters or port accesses** had been used **continuously** in this patient for the past **90 days or longer** between OCT 1, 2003 and DEC 31, 2003.

#### **Unknown:**

If the vascular access in question 21 is unknown indicate by checking the "unknown" box and then continue to question 22.

- 22: Check the appropriate space to indicate if the patient FIRST started hemodialysis during January 1, 2003-August 31, 2003 (see date #8 on page 1). These patients would have begun a regular maintenance course of hemodialysis during January 1, 2003-August 31, 2003. DO NOT include patients who have transferred from peritoneal dialysis, had a newly failed trans plant, or returned after an episode of regained kidney function, and were placed on maintenance hemodialysis during the time frame January 1, 2003-August 31, 2003. If "Yes", answer questions 22A-B. If "No", questions 22A-B should be left blank and the form has been completed.
- **22A:** Check the appropriate space to indicate type of vascular access in use upon **Initiation** of a maintenance course of hemodialysis (see date #8 on page 1) during the time frame January 1, 2003-August 31, 2003. Exclude patients who have received intermittent dialysis treatments for volume overload or congestive heart failure. ("Port Access" is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).
- **22B:** Check the appropriate space to indicate type of vascular access, for the patient identified in 22A, **in use 90 days after** the patient first started hemodialysis. ("Port Access" is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).

#### Appendix 3. 2003 CPM Data Collection Form – Peritoneal Dialysis

# PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004

[Before completing please read instructions at the bottom of this page and on pages 5 and 6]

PATIENT IDENTIFICATION	MAKE CORRECTIONS TO PATIENT INFORMATION ON LABEL IN THE SPACE BELOW
Place Patient Data Label Here	
12. If this patient is unknown or was not dialyzed in the facility at a	any time during OCT 2003-MAR 2004 return the blank
form to the Network.	
13. Patient's Ethnicity (Check appropriate box). ☐ non-Hispanic ☐	
☐ Hispanic, Puerto Rican ☐ Hispanic, Cuban American ☐ H	Hispanic, Other 🖵 Unknown
14a.Patient's height (MUST COMPLETE):inches	ORcentimeters
14b.Patient's weight (abdomen empty) (first clinic visit weight after	Oct. 1, 2003):lbs. OR kg.
15. Did patient have limb amputation(s) prior to Mar. 31, 2004:	☐ Yes ☐ No ☐ Unknown
16. Has the patient ever been diagnosed with any type of diabetes?	☐ Yes (go to 17) ☐ No (go to 18) ☐ Unknown (go to 18)
17. If question 16 was answered YES, was the patient taking medication	ns to control the diabetes during the study period?
☐ Yes ☐ No ☐ Unknown If YES, was the patient using insu	lin during the study period?
Individual Completing Form (Please print):	
First name: Last name:	Title:
Phone number: ( Fax number	: (

#### INSTRUCTIONS FOR COMPLETING THE PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004

The label on the top left side of this form contains the following patient identifying information (#'s 1-11). If the information is incorrect make corrections to the right of the label.

- 1. LAST and first name.
- 3. SOCIAL Security Number (SSN).
- 5. GENDER (1=Male; 2=Female).
- 7. PRIMARY cause of renal failure by CMS-2728 code.
- ESRD Network number.Do not make corrections to this item.
- 2. DATE of birth (DOB) as MM/DD/YYYY.
- 4. HEALTH Insurance Claim Number (HIC), (same as Medicare number).
- 6. RACE (1=American Indian/Alaska Native; 2=Asian; 3=Black; 4=White; 5=Unknown; 6=Pacific Islander; 7=Mid East Arabian; 8=Indian Subcontinent; 9=Other Multiracial).
- 8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.
- 10. Facility's Medicare provider number.
- 11. The most RECENT date this patient returned to peritoneal dialysis following: transplant failure, an episode of regained kidney function, or switched modality.
- 12. If the patient is unknown or if the patient was not dialyzed in the facility at any time during OCT 2003 through MAR 2004, send the blank form back to the ESRD Network office. Provide the name and address of the facility providing services to this patient on December 31, 2003, if known.
- 13. Patient's Ethnicity. Please verify the patient's ethnicity with the patient and check appropriate box.
- 14a.Enter the patient's height in inches or centimeters. HEIGHT MUST BE ENTERED, do not leave this field blank. You may ask the patient his/her height to obtain this information. If the patient had both legs amputated, record pre-amputation height and check YES for item 15.
- 14b.Enter the patient's weight (abdomen empty) in pounds or kilograms. Use the FIRST CLINIC VISIT weight on or after October 1, 2003.
- 15. For the purpose of this study, check NO if this patient has had toe(s), finger(s), or mid-foot (Symes) amputation; but check YES if this patient has had a below-knee, below-elbow, or more proximal (extensive) amputation prior to Mar. 31, 2004.
- 16. Check either "Yes", "No", or "Unknown" to indicate if the patient has ever been diagnosed with any type of diabetes. If **YES**, proceed to question 17.
- 17. Check either "Yes", "No", or "Unknown" to indicate if the patient was taking medications to control the diabetes during the study period. If the answer to 17 is **YES**, please check either "Yes", "No", or "Unknown" to indicate if the patient was using insulin during the study period. Study period is OCT 2003 -MAR 2004.

#### PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)

18. ANEMIA MANAGEMENT: For each lab question below, enter the first lab value obtained for each two-month time period: OCT-NOV 2003, DEC 2003-JAN 2004, FEB-MAR 2004. Enter NF/NP if the lab value cannot be located.

	OCT-NOV 2003	DEC 2003-JAN 2004	FEB-MAR 2004
A. First laboratory hemoglobin (Hgb) during the two-month time period:	g/dL (If NF/NP go to 18C)	g/dL	g/dL (If NF/NP go to 18C)
B.1.a. Did the patient receive Epoetin at anytime during the 30 days before the Hgb in 18A was drawn?	Epoetin:  Yes No Unknown	Epoetin: □ Yes o No □ Unknown	Epoetin: □ Yes □ No □ Unknown
B.1.b. Did the patient receive Darbepoetin (Aranesp <sup>TM</sup> ) at anytime during the 30 days before the Hgb in 18A was drawn?	Darbepoetin: □ Yes □ No □ Unknown	Darbepoetin: □ Yes □ No □ Unknown	Darbepoetin: □ Yes □ No □ Unknown
B.2.a. What was the PRESCRIBED Epoetin dose in units/month at the time immediately BEFORE the Hgb in 18A was drawn? (See instructions on page 5)	Epoetin: units/month	Epoetin:units/month	Epoetin: units/month
B.2.b.What was the PRESCRIBED Darbepoetin dose in micrograms for the MONTH immediately BEFORE the Hgb in 18A was drawn? (See instructions on page 5)	Darbepoetin: mcg/month	Darbepoetin: mcg/month	Darbepoetin: mcg/month
B.3.a. How many times per month was Epoetin prescribed?	Epoetin: x per month	Epoetin: x per month	Epoetin:x per month
B.3.b. How many times per month was Darbepoetin prescribed?	Darbepoetin: x per month	Darbepoetin: x per month	Darbepoetin: x per month
B.4.a. What was the prescribed route of administration for Epoetin? (Check all that apply)	Epoetin: o IV o SC o Unknown	Epoetin: o IV o SC o Unknown	Epoetin: o IV o SC o Unknown
B.4.b. What was the prescribed route of administration for Darbepoetin? (Check all that apply)	Darbepoetin: ☐ IV ☐ SC ☐ Unknown	Darbepoetin: □ IV □ SC □ Unknown	Darbepoetin: ☐ IV ☐ SC ☐ Unknown
C. First serum ferritin concentration during the two-month time period:	ng/mL	ng/mL	ng/mL
D. First % transferrin (iron) saturation during the two-month time period:	%	%	%
E. Was iron prescribed at any time during the two- month time period?	☐ Yes ☐ No (go to 19) ☐ Unknown (go to 19)	☐ Yes ☐ No (go to 19) ☐ Unknown (go to 19)	☐ Yes ☐ No (go to 19) ☐ Unknown (go to 19)
F. If yes, what was the prescribed route of iron administration? (Check all that apply).	□ IV □ PO □ Unknown	□ IV o PO □ Unknown	□ IV □ PO □ Unknown
G. If the patient was prescribed IV iron, what was the total dose of IV iron administered during the two-month time period?	mg	mg	mg
19. SERUM ALBUMIN: Enter the first serum album 2004, FEB-MAR 2004. Enter NF/NP if the lab value bromcresol purple) by the lab to determine serum al	e cannot be located. Chec	k the method used (BCG/	
	OCT-NOV 2003	DEC 2003-JAN 2004	FEB-MAR 2004
A. First serum albumin during the two-month time period:	g/dL	• g/dL	• g/dL
B. Check lab method used: BCG = bromcresol green; BCP = bromcresol purple	□BCG □ BCP	□ BCG □ BCP	□ BCG □ BCP
20. PERITONEAL DIALYSIS ADEQUACY: The re measurements for this patient. Please answer questic cated. Then continue to pages 3 and 4.			
	OCT-NOV 2003	DEC 2003-JAN 2004	FEB-MAR 2004
A. Was the patient on peritoneal dialysis at any time during this period?	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown
B. Was the patient on hemodialysis or did patient	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
receive a transplant at any time during this period?	☐ Unknown	☐ Unknown	☐ Unknown

#### PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)

21. ADEQUACY: The following data a ADEQUACY determination during the part through MARCH 2004. Starting with the ment in these months, enter the adequace listed below that were obtained. (Please one adequacy measurement done for any instructions on Pages 5 and 6 before con NF/NP if information cannot be located.	months OCTOBER 2003 e first adequacy measure- y measurements/results DO NOT record more than y one month.) Please read upleting this section. Enter	22. PERITONEAL DIALYSIS PRE following questions – record the PD time the adequacy measures/results performed. Please read instructions this section. Enter NF/NP if informations	prescription in effect at the recorded in Question 21 were on Page 6 before completing
21. Was adequacy measurement done during OCT 2003-MAR 2004?	☐ Yes ☐ No ☐ Unknown		Prescription at the time adequacy was measured in 21A
21A. Date of <b>FIRST</b> adequacy measurement between 10-1-2003 to 3-31-200	4 (mm) (dd) (yyyy)	22A. CAPD PRESCRIPTION (this includes patients with one overnight exchange using an	
21B. Patient's dialysis modality when adequacy measures were performed	☐ CAPD ☐ Cycler (See definitions in instructions on p. 5)	assist device)  1. Number of dialysis days per	
21C. Patient's weight at the time of this adequacy assessment (abdomen empty) (Circle lbs or kgs)	lbs /kgs	week  2. Total dialysate volume infused per 24 hours	(# days)
21D. Weekly Kt/V <sub>urea</sub> (dialysate and urine clearance)		Total number of exchanges     per 24 hours (including     overnight exchange)	mL/24 hrs  (# exchanges)
21E. Method by which V above was calculated: Check one. (If unknown please call lab.)	□ %BW □ Hume □ Watson □ Other	22B. CYCLER PRESCRIPTION  1. Number of dialysis days per week	(# days)
21F. Weekly Creatinine Clearance (dialysate and urine clearance)	L/wk	2. Total dialysate volume infused per 24 hours	mL/24 hrs
21G. Is this Creatinine Clearance corrected for body surface area, using standard methods? (See instructions on page 6)	□ Yes □ No □ Unknown	Total dialysis time     a. Total nighttime dialysis time     b. Total daytime dialysis time     c. Total amount of time the     patient is dry during     24 hours	hrsminhrsminhrsmin
21H. 24 hr DIALYSATE <b>volume</b> (prescribed and ultrafiltration)	mL	(Note: 3a+b+c = 24 hours) 4. Nighttime Prescription	
21I. 24 hr DIALYSATE <b>urea nitrogen</b> :	mg/dL	nighttime exchange	mL/exchange
21J. 24 hr DIALYSATE <b>creatinine</b> :	mg/dL	b. Number of dialysis exchanges during the	(11/:14/:)
21K. 24 hr URINE <b>volume</b> : (If 24 hr urine was not located check NF/NP.)	mL	nighttime  5. Daytime Prescription (including last bag fill) a. Volume of a single	(#/nighttime)
21L. 24 hr URINE <b>urea nitrogen</b> :	mg/dL	daytime exchange	mL/exchange
21M. 24 hr URINE creatinine:	mg/dL	b. Number of dialysis exchanges during the	
21N. SERUM BUN at the time this adequacy assessment was done	mg/dL	daytime  6. Does the cycler prescription	(#/daytime)
210. SERUM creatinine at the time this adequacy assessment was done	mg/dL	described above include TIDAL dialysis?	□ Yes □ No □ Unknown
<ul> <li>21P.1. Most recent 4 hour dialysate/plasma creatinine ratio (D/P Cr) from a peritoneal equilibration test (PET).</li> <li>2. Date of most recent D/P Cr</li> </ul>	(mm) / (dd) / (yyyy)	<ul><li>22C. Based on the adequacy result from questions 21A-O,</li><li>1. Was the collection repeated?</li><li>2. Was the prescription changed?</li></ul>	☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown

APPENDICES (APPENDIX 3)			81
PERITONEAL DIALYSIS CLINIC	CAL PERFORMANCE ME	CASURES DATA COLLECTION FOR	R 2004: (CONTINUED)
23. ADEQUACY: The following data are OND ADEQUACY determination during 2003 through MARCH 2004. Starting wit measurement in these months, enter the a results listed below that were obtained. (For more than one adequacy measurement do Please read instructions on Page 6 before Enter NF/NP if information cannot be located as a superior of the property	the months NOVEMBER h the second adequacy dequacy measurements/ clease DO NOT record one for any one month.) completing this section.	24. PERITONEAL DIALYSIS PRE following questions – record the PD time the adequacy measures/results performed. Please read instructions this section. Enter NF/NP if informations	prescription in effect at the recorded in Question 23 were on Page 6 before completing
23. Was second adequacy measurement done during NOV 2003-MAR 2004?	□ Yes □ No □ Unknown		Prescription at the time adequacy was measured in 23A
23A. Date of <b>SECOND</b> adequacy measure ment between 11-1-2003 to 3-31-2004		24A. CAPD PRESCRIPTION (this includes patients with one overnight exchange using an	
23B. Patient's dialysis modality when adequacy measures were performed	☐ CAPD ☐ Cycler (See definitions in instructions on p. 5)	assist device)  1. Number of dialysis days per week	
23C. Patient's weight at the time of this adequacy assessment (abdomen empty) (Circle lbs or kgs)	lbs /kgs	Total dialysate volume infused per 24 hours     Total number of exchanges	mL/24 hrs
23D. Weekly Kt/V <sub>urea</sub> (dialysate and urine clearance)		per 24 hours (including overnight exchange)	(# exchanges)
23E. Method by which V above was calculated: Check one. (If unknown please call lab)	□ %BW □ Hume □ Watson □ Other	24B. CYCLER PRESCRIPTION  1. Number of dialysis days per week	
23F. Weekly Creatinine Clearance (dialysate and urine clearance)	L/wk	2. Total dialysate volume infused per 24 hours	mL/24 hrs
23G. Is this Creatinine Clearance corrected for body surface area, using standard methods? (See instructions on page 6)	☐ Yes ☐ No ☐ Unknown	Total dialysis time     a. Total nighttime dialysis time     b. Total daytime dialysis time     c. Total amount of time the     patient is dry during	hrsminhrsmin
23H. 24 hr DIALYSATE <b>volume</b> (prescribed and ultrafiltration)	mL	24 hours (Note: 3a+b+c = 24 hours) 4. Nighttime Prescription	hrsmin
23I. 24 hr DIALYSATE <b>urea nitrogen</b> :	mg/dL	(excluding last bag fill) a. Volume of a single	<del></del> -
23J. 24 hr DIALYSATE <b>creatinine</b> :	mg/dL	nighttime exchange b. Number of dialysis	mL/exchange
23K. 24 hr URINE <b>volume</b> : (If 24 hr urine was not located check NF/NP.)	mL	exchanges during the nighttime  5. Daytime Prescription (including last bag fill)	(#/nighttime)
23L. 24 hr URINE <b>urea nitrogen</b> :	mg/dL	a. Volume of a single daytime exchange	<del></del>
23M. 24 hr URINE <b>creatinine</b> :	mg/dL	b. Number of dialysis exchanges during the	mL/exchange
23N. SERUM BUN at the time this adequacy assessment was done	mg/dL	daytime  6. Does the prescription described	(#/daytime)
23O. SERUM creatinine at the time this adequacy assessment was done	mg/dL	above include TIDAL dialysis?	□Yes □No □Unknown
23P.1.If the patient has had a 4-Hour D/P Cr performed from a PET since the time of the first adequacy test, enter the value and the date the test was performed.	/	<ul><li>24C. Based on the adequacy result from questions 23A-O,</li><li>1. Was the collection repeated?</li><li>2. Was the prescription changed?</li></ul>	☐ Yes ☐ No ☐ Unknown

(mm) / (dd) / (yyyy)

2. Was the prescription changed?

☐ Yes ☐ No ☐ Unknown

If not performed, enter NP.

#### PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)

INSTRUCTIONS FOR COMPLETING QUESTIONS 18 THROUGH 20 (continued from page 1): To answer questions 18 through 20 review the patient's clinic or facility medical record FOR EACH TWO-MONTH TIME PERIOD: OCT 1, 2003 through NOV 30, 2003, DEC 1, 2003 through JAN 31, 2004, and FEB 1, 2004 through MAR 31, 2004. Do not leave any items blank. Enter NF/NP if the following information cannot be located.

- **18A:** Enter the patient's FIRST hemoglobin (Hgb) value determined by the laboratory for EACH two-month time period. If not found or not performed during the two-month time period, enter NF/NP.
- **18B.1:** Check the appropriate box to indicate if the patient received EPOETIN or DARBEPOETIN (Aranesp<sup>™</sup>) at anytime during the 30 days BEFORE the date of the hemoglobin value in 18A. If the answer is NO to both, skip to question 18C.
- **18B.2:** If **Epoetin** was prescribed, enter the PRESCRIBED MONTHLY Epoetin dose, **not the administered dose**, in units given at the time immediately before the hemoglobin value in 18A, even if the patient did not receive the dose. This includes any prescribed dose not given because of an error or the patient missed a dose, etc. Enter "0" if the patient was on "Hold". (For the purposes of this collection, a "Hold" order will be considered a 0 unit prescribed dose.)
  - If **Darbepoetin** (Aranesp<sup>TM</sup>) was prescribed, enter the PRESCRIBED MONTHLY Darbepoetin dose, **not the administered dose**, in micrograms per month during the month immediately before the date of the hemoglobin value in 18A, even if the patient did not receive the dose. This includes any prescribed dose not given because of an error or the patient missed a dose, etc. Enter "0" if the patient was on "Hold". (For the purposes of this collection, a "Hold" order will be considered a 0 mcg/month prescribed dose.)
- 18B.3: Enter the number of times per month that Epoetin was prescribed OR the number of times per month Darbepoetin was prescribed.
- **18B4:** Check the appropriate box to indicate the prescribed route of administration for Epoetin or for Darbepoetin (intravenous [IV] or subcutaneous [SC]). If the patient received Epoetin or Darbepoetin IV and SC during the month, please check both boxes.
- **18C:** Enter the patient's FIRST serum ferritin concentration recorded EACH two-month time period. If a serum ferritin concentration test was not found or not performed every two-month time period, enter the value for the time period when performed and record NF/NP for the other time period(s).
- **18D:** Enter the patient's FIRST % transferrin (iron) saturation recorded EACH two-month time period. If a % transferrin (iron) saturation test was not found or not performed every two-month time period, enter the value for the time period when performed and record NF/NP for the other time period(s).
- 18E: Check either "Yes", "No", or "Unknown" to indicate if iron was prescribed at any time during the two-month time periods.
- **18F**: If the answer to 18E is "Yes", please check the appropriate space to indicate the route of iron administration (intravenous [IV] or by mouth [PO]) for each two-month time period. Check every route of administration that was prescribed each time period.
- **18G:** If the patient was prescribed IV iron, add together all doses that were given during each two-month time period OCT-NOV 2003, DEC 2003-JAN 2004, FEB-MAR 2004 and enter the TOTAL dose of IV iron (in mg) **administered**.
- 19A: Enter the patient's FIRST serum albumin value recorded EACH two-month time period.
- **19B:** Check the method used by the laboratory to determine the serum albumin levels (bromcresol green or bromcresol purple). If you do not know what method the laboratory used, call the laboratory to find out this information.
- **20A:** Check the appropriate response (yes or no) for each two-month time period, indicating whether this patient was on peritoneal dialysis at any time during each of the specified two-month time periods.
- 20B: Check the appropriate response (yes or no) for each two-month time period, indicating whether this patient was on hemodialysis or received a transplant at any time during each of the specified two-month time periods.

INSTRUCTIONS FOR COMPLETING QUESTIONS 21 THROUGH 24: To answer questions 21 through 24 review the patient's clinic or facility medical record and provide the requested data for each of the first two adequacy measurements and PD prescriptions in effect at the time the adequacy measurements were done during the months OCTOBER 2003 through MARCH 2004. DO NOT record more than one adequacy measurement done for any one month.

- 21. Check "yes", "no", or "unknown" to indicate if an adequacy measurement was done between OCT 1, 2003 through MAR 31, 2004.
- 21A: Enter the first date on which adequacy of dialysis was assessed for the first measure obtained between OCT 1, 2003 through MAR 31, 2004. DO NOT record more than one adequacy measurement done for any one month.
- 21B: Check the modality of peritoneal dialysis this patient was on at the time the corresponding adequacy of dialysis measure was obtained. CHECK either CAPD or Cycler. CAPD includes patients with one overnight exchange using an assist device. Cycler includes patients using an automated device for exchanges.
- 21C: Enter the patient's weight (with abdomen empty) at the clinic/facility visit when the adequacy measurements were obtained, circle lbs or kgs as appropriate.
- 21D: Enter the TOTAL WEEKLY Kt/V<sub>urea</sub> for the first adequacy measurement indicated on 21A between OCT 1, 2003 through MAR 31, 2004. NOTE: Whether or not you have a value for weekly Kt/V<sub>urea</sub> for this adequacy assessment, please complete the corresponding values for questions 21H-21I for 24-hour dialysate volume, 24-hour dialysate urea and question 21K for 24-hour urine volume. If the patient is not anuric, complete the corresponding value for question 21L, the 24-hour urine urea, if this value is available. Enter NF/NP for all values when not found or not performed. If your unit calculates a daily Kt/V<sub>urea</sub>, multiply this result by 7.0 and enter the result in the appropriate space(s). If this patient did not dialyze each day of the week, then multiply the daily Kt/V<sub>urea</sub> by the number of days the patient did dialyze.

#### PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)

- 21E: Check the method used to calculate the V in the Kt/V urea measurement; % BW = percent of body weight; Hume and Watson are two nomograms used to calculate V based on several of these parameters weight, height, age, gender. If method used to calculate V is not known, please call lab to ascertain method. Please do not leave blank.
- 21F: Enter the TOTAL WEEKLY CREATININE CLEARANCE for the first adequacy measurement indicated on 21A between OCT 1, 2003 through MAR 31, 2004. NOTE: Whether or not you have a value for weekly creatinine clearance for this adequacy assessment, please complete the corresponding values for questions 21H and 21J for 24-hour dialysate volume, 24-hour dialysate creatinine and question 21K for 24-hour urine volume. If the patient is not anuric, complete the corresponding value for question 21M, the 24-hour urine creatinine, if this value is available. Enter NF/NP for all values when not found or not performed. If your unit calculates a daily creatinine clearance multiply this result by 7.0 and enter the result in the appropriate space(s). If this patient did not dialyze each day of the week, then multiply the daily creatinine clearance by the number of days the patient did dialyze.
- 21G: Check Yes or No if the weekly creatinine clearance was normalized for body surface area (i.e., the result is multiplied by 1.73m² and divided by the patient's body surface area [BSA]). Standard methods for establishing BSA are: the DuBois and DuBois method; the Gehan and George method; and the Haycock method. If you do not have this information, call the laboratory that provided the creatinine clearance value for this information. Please do not leave blank.
- 21H, I, and J: Enter the measured 24-hour DIALYSATE volume (includes prescribed and ultrafiltration volumes), urea nitrogen and creatinine obtained for the first adequacy measurement obtained between OCT 1, 2003 through MAR 31, 2004. If a 24-hour dialysate volume, urea nitrogen or creatinine were NOT measured in this time period, enter NF/NP (for not found or not performed) in the appropriate spaces. ONLY ENTER ACTUAL MEASURED 24-HOUR DIALYSATE VOLUME. DO NOT ENTER AN EXTRAPOLATED DIALYSATE VOLUME. Please report the 24-hour dialysate volume as a combination of the prescribed fill volume and the ultrafiltration volume.
- 21K, L, and M: Enter the 24-hour URINE volume, urea nitrogen and creatinine obtained for the first adequacy assessment obtained between OCT 1, 2003 through MAR 31, 2004. ONLY ENTER ACTUAL MEASURED 24-HOUR URINE VOLUME—DO NOT ENTER AN EXTRAPOLATED URINE VOLUME. If 24-hour urine volume was not collected check NF/NP for not found or not performed. If NF/NP is checked, SKIP TO QUESTION 21N. If urine urea nitrogen and creatinine were not found or not measured in this time period, enter NF/NP in the appropriate spaces.
- **21N, O:** Enter the SERUM BUN and SERUM CREATININE obtained for the first adequacy assessment obtained between OCT 1, 2003 through MAR 31, 2004. Enter NF/NP in the appropriate spaces for all time periods when not found or not performed.
- 21P: (1) Enter the most recent four hour dialysate/plasma creatinine ratio (D/P Cr) from a peritoneal equilibration test (PET).(2) Enter the date of the most recent D/P Cr. The test result and corresponding date of the most recent D/P Cr may be outside the 6-month study period. If never found or performed record NF/NP. Date cannot be after 3/31/04 or prior to the first day of peritoneal dialysis.
- 22: To respond to questions 22A through 22C record the peritoneal dialysis (PD) prescription in effect at the time of the first adequacy measures/results recorded in question 21 performed between OCT 1, 2003 through MAR 31, 2004. Complete all items that are applicable.
- 22A: CAPD PRESCRIPTION. Use the CAPD prescription category for all CAPD patients including patients with one overnight exchange using an assist device. (1) Enter the number of days per week for which this patient underwent peritoneal dialysis. (2) Enter the total dialysate volume in mL infused over a 24-hour period and (3) the number of exchanges per 24-hour period PRESCRIBED for CAPD at the time the first adequacy measurements were performed.
- 22B: CYCLER PRESCRIPTION. (1) Enter the number of days per week for which this patient underwent peritoneal dialysis. (2) Enter the total dialysate volume in mL infused over a 24-hour period. (3) Total dialysis time (Note: 2a+b+c = 24 hours): (3a) Enter the total nighttime dialysis time, (3b) the total daytime dialysis dwell time, and (3c) the total amount of time the patient is dry during 24 hours. If the patient is never dry in 24 hours enter a value of 0 hours. The hours entered in 2a, b, & c should equal 24 hours. (4) Nighttime Prescription (excluding last bag fill): (4a) Enter the volume of a single nighttime exchange and (4b) the number of dialysis exchanges during the nighttime PRESCRIBED for CYCLER NIGHTTIME at the time the first adequacy measurements were performed. Include in the CYCLER NIGHTTIME prescription only those exchanges provided by an automated device. DO NOT include in this category any last bag fill or option that the patient carries after unhooking from the cycler or any daytime dwells as these exchanges are recorded in the DAYTIME PRESCRIPTION information. If different inflow volumes are used, report average inflow volume. (5) Daytime Prescription (including last bag fill): (5a) Enter the volume of a single daytime exchange and (5b) the number of dialysis exchanges during the daytime PRESCRIBED for CYCLER DAYTIME at the time the first adequacy measurements were performed. Include in the CYCLER DAYTIME prescription only those exchanges performed after the patient disconnects from the cycler and/or a last bag fill or option that the patient carries during the day. ANY OTHER EXCHANGES PERFORMED USING THE CYCLER SHOULD BE INCLUDED UNDER CYCLER NIGHTTIME PRESCRIPTION. If different inflow volumes are used, report average inflow volume.
  - (6) Check the appropriate box, "yes" or "no", indicating whether this patient's peritoneal dialysis prescription included TIDAL dialysis. TIDAL patients are cycler patients for whom the dialysate is partially drained between some exchanges.
- **22C:** (1) Check the appropriate box, "yes" or "no", indicating whether the adequacy collection was repeated, and (2) check the appropriate box "yes" or "no", indicating whether the prescription changed following the first adequacy measurement performed between OCT 1, 2003 through MAR 31, 2004.
- 23: Check "yes", "no", or "unknown" to indicate if an adequacy measurement was done between NOV 1, 2003 through MAR 31, 2004.
- **23A-O:** See instructions for 21A-21O and complete for second adequacy measurement performed between NOV 1, 2003 through MAR 31, 2004. DO NOT record more than one adequacy measurement done for any one month.
- 23P: Record the value and date of the patient's PET if a new one was performed since the time of the first adequacy test. If not performed enter NP.
- **24A-C:** See instructions for 22A-22C and complete for the peritoneal dialysis (PD) prescription in effect at the time of the second adequacy measures/results recorded in question 23 performed between NOV 1, 2003 through MAR 31, 2004.

#### Appendix 4. Centers for Medicare & Medicaid Services (CMS) Offices and ESRD Networks

#### **CMS Offices**

(410) 786-5785

Centers for Medicare & Medicaid Services
Office of Clinical Standards & Quality
Quality Measurement and Health Assessment
Group
Mailstop S3-02-01
7500 Security Boulevard
Baltimore, MD 21244

Centers for Medicare & Medicaid Services -Region I Division of Clinical Standards and Quality, Clinical Standards Branch Room 2275 JFK Federal Building Boston, MA 02203-0003 (617) 565-3136

Centers for Medicare & Medicaid Services -Region VI Division of Clinical Standards and Quality Room 714 1301 Young Street Dallas, TX 75202 (214) 767-4443

Centers for Medicare & Medicaid Services -Region VII Division of Clinical Standards and Quality, Medical Review Branch Richard Bolling Federal Building 60I East I2th Street, Room 242 Kansas City, MO 64106-2808 (816) 426-5746

Centers for Medicare & Medicaid Services -Region X Division of Clinical Standards and Quality 2201 Sixth Avenue, Mail Stop (RX-42) Seattle, WA 98121-2500 (206) 615-2317

#### **ESRD Networks**

ESRD Network Organization No. 1 ESRD Network of New England, Inc. 30 Hazel Terrace Woodbridge, CT 06525 Region I: ME, NH, VT, MA, CT, RI (203) 387-9332

ESRD Network Organization No. 2 ESRD Network of New York, Inc. 1249 Fifth Avenue A-419 New York, NY 10029 Region I: NY (212) 289-4524 ESRD Network Organization No. 3 TransAtlantic Renal Council Cranbury Gates Office Park 109 South Main Street, Suite 21 Cranbury, NJ 08512-9595 Region I: NJ, PR, VI (609) 490-0310

ESRD Network Organization No. 4 40 24th Street, Suite 410 Pittsburgh, PA 15222 Region: DE, PA (412) 325-2250

ESRD Network Organization No. 5 Mid-Atlantic Renal Coalition 1527 Huguenot Road Midlothian, VA 23113 Region I: DC, MD, VA, WV (804) 794-3757

ESRD Network Organization No. 6 Southeastern Kidney Council, Inc. 1000 St. Albans Drive Suite 270 Raleigh, NC 27609 Region VI: GA, NC, SC (919) 855-0882

ESRD Network Organization No. 7 FMQAI: The Florida ESRD Network 4350 West Cypress Street, Suite 900 Tampa, FL 33607 Region: FL (813) 383-1530

ESRD Network Organization No. 8 Network Eight, Inc. P.O. Box 55868 Jackson, MS 39296-5868 Region VI: AL, MS, TN (601) 936-9260

ESRD Network Organization No. 9 & 10 The Renal Network, Inc. 911 East 86th Street, Suite 202 Indianapolis, IN 46240-1858 Region VII: KY, IN, OH, IL (317) 257-8265

ESRD Network Organization No. 11 Renal Network of the Upper Midwest, Inc. 1360 Energy Park Drive, Suite 200 St. Paul, MN 55108 Region: MI, MN, ND, SD, WI (651) 644-9877

ESRD Network Organization No. 12 7505 NW Tiffany Springs Parkway, Suite 230 Kansas City, MO 64153 Region VII: MO, IA, NE, KS (816) 880-9990 ESRD Network Organization No. 13 4200 Perimeter Center Drive, Suite 102 Oklahoma City, OK 73112-2314 Region: AR, LA, OK (405) 942-6000

ESRD Network Organization No. 14 ESRD Network of Texas, Inc. 14114 Dallas Parkway, # 660 Dallas, TX 75240-4349 Region VI: TX (972) 503-3215

ESRD Network Organization No. 15 Intermountain ESRD Network, Inc. 1301 Pennsylvania Street, Suite 750 Denver, CO 80203-5012 Region X: NM, CO, WY, UT, AZ, NV (303) 831-8818

ESRD Network Organization No. 16 Northwest Renal Network 4702 42nd Avenue, SW Seattle, WA 98116 Region X: MT, AK, ID, OR, WA (206) 923-0714

ESRD Network Organization No. 17 TransPacific Renal Network 4470 Redwood Highway, Suite 102 San Rafael, CA 94903 Region X: No. CA, HI, Mariana Isl., GU, AS (415) 472-8590

ESRD Network Organization No. 18 Southern California Renal Disease Council, Inc. 6255 Sunset Boulevard, Suite 2211 Los Angeles, CA 90028 Region X: So. CA (323) 962-2020

#### **Appendix 5. ESRD CPM Quality Improvement Committee Members**

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Aaron Friedman, MD + Madison, WI 53792-4108

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Alicia M. Neu, MD + Baltimore, MD 21287-2535

Bradley Warady, MD + Kansas, City, MO 64108

Sandra Watkins, MD + Seattle, WA 98195-9300

- ^ Peritoneal Dialysis Subcommittee Member
- \* Vascular Access Subcommittee Member
- + Pediatric Subcommittee Member

## Appendix 6. List of Publications/Abstracts/Supplemental Reports of ESRD CPM and Core Indicators Data

#### **Adult Publications**

- McClellan WM, Frederick P, Helgerson S, Hayes R, Ballard D, McMullan M. A Health Care Quality Im-provement Program for End-Stage Renal Disease (ESRD). Health Care Financing Review 1995. 16;129-140.
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- McClellan Wm. Quality of patient care in the Medicare End-Stage Renal Disease (ESRD) Program: The basis and implementation of the 1994-1997 ESRD Health Care Quality Improvement Program (HCQRP). Nephrology and Hypertension 1996; 5:224-229.
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- Rocco MV, Flanigan MJ, Beaver S, Frederick P, Gentile DE, McClellan WM, Polder J, Prowant BF, Taylor L, Helgerson SD. Report from the 1995 Core Indicators for Peritoneal Dialysis Study Group. Am J Kidney Dis 1997; 30:165-173.
- Flanigan MJ, Rocco MV, Frankenfield DL, Bailie G, Frederick PR, Prowant BF, Taylor L. 1996 Peritoneal Dialysis-Core Indicators Report. Am J Kidney Dis 1998; 32:1-9.
- Flanigan MJ, Bailie GR, Frankenfield DL, Frederick PR, Prowant BF, Rocco MV. 1996 Peritoneal Dialysis Core Indicators Study: Report on nutritional indicators. Perit Dial Intl 1998; 18:489-496.
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- Owen WF Jr., Szczech L, Johnson C, Frankenfield D. National perspective on iron therapy as a clinical performance measure for maintenance hemodialysis patients. Am J Kidney Dis 1999; 34 (Suppl 2):S5-S11.
- Frankenfield DL, Rocco MV, Frederick PR, Pugh J, McClellan WM, Owen WF Jr. Racial/ethnic analysis of selected intermediate outcomes for hemodialysis patients: Results from the 1997 ESRD Core Indicators Project Am J Kidney Dis 1999; 34:721-730.
- McClellan WM, Frankenfield DL, Frederick PR, Flanders WD, Alfaro-Correa A, Rocco M, Helgerson SD. Can dialysis therapy be improved? A Report from the ESRD Core Indicators Project. Am J Kidney Dis 1999; 34:1075-1082.
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- Sugarman JR, Frederick PR, Frankenfield DL, Owen WF Jr., McClellan WM. Developing clinical performance measures based on the Dialysis Outcomes Quality Initiative Clinical Practice Guidelines: Process, outcomes, and implications. Am J Kidney Dis 2003;42:806-812.
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#### **Pediatric Publications**

- Frankenfield DL, Neu AM, Warady BA, Fivush BA, Johnson CA, Brem AS. Anemia in pediatric hemodialysis patients: Results from the 2001 ESRD Clinical Performance Measures Project. Kidney International 2003;64:1120-1124.
- Neu AM, Fivush BA, Warady BA, Watkins SL, Friedman AL, Brem AS, Goldstein S, Frankenfield DL. Longitudinal analysis of intermediate outcomes in adolescent hemodialysis patients. Pediatric Nephrology 2003;18:1172-1176.
- Neu AM, Bedinger MR, Fivush BA, Warady BA, Watkins SL, Friedman AL, Brem AS, Goldstein SL, Frankenfield DL. Growth in adolescent hemodialysis patients: Data from the Centers for Medicare & Medicaid Services ESRD Clinical Performance Measures Project. Pediatric Nephrology [in press].
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#### **Supplemental Reports**

#### 1994

#### Supplemental Report #1

Results of validation study: comparison of data abstracted by ESRD facility staff and by ESRD Network staff (April 1995)

#### Supplemental Report #2

Questions and answers regarding core indicator results for a variety of facility and patient characteristics (May 1995)

#### Supplemental Report #3

The mortality and morbidity experience from January through June 1994 for patients described by core indicators values in October through December, 1993 (October 1995)

#### Special Populations Report

Results for American Indians and Alaska Natives identified in the 1994 ESRD Core Indicators Project (April 1995)

#### 1995

#### Supplemental Report # 1

\*Association of body weight with adequacy of dialysis (August 1996)

#### Special Populations Report

Results for American Indians and Alaska Natives receiving incenter hemodialysis in ESRD Networks 11, 15, and 16 (September 1996)

#### 1996

#### Special Report #A

Results of 1996 validation study: Analysis of concurrence between Core Indicators data abstracted by dialysis facility staff and ESRD Network staff (April 1997)

#### Special Report #B

Influenza immunization of ESRD patients October, November, and December 1995 (July 1997)

#### Supplemental Report #1

Predictors for a delivered hemodialysis treatment of < 0.65 URR (March 1997)

#### Supplemental Report #2

Sub-optimal serum albumin levels of adult, in-center hemodialysis patients: Results from the 1996 ESRD Core Indicators Project (May 1997)

#### Supplemental Report #3

Description of a cohort's experience: ESRD Core Indicators Project, 1993-1995 (June 1997)

#### Supplemental Report #4

Gender analysis of the 1996 ESRD Core Indicators data (December 1997)

#### 1997

#### Special Report #A

Results of 1997 validation study: Analysis of concurrence between Core Indicators data abstracted by dialysis facility staff and ESRD Network staff (May 1998)

#### Supplemental Report #1

\*Analysis of Core Indicators results by race/ethnicity for adult (aged ≥ 18 years) in-center hemodialysis and peritoneal dialysis patients (February 1998)

#### Supplemental Report #2

\*Adequacy measures for adult peritoneal dialysis patients (March 1998)

#### Supplemental Report #3

\*The management of anemia in adult in-center hemodialysis and peritoneal dialysis patients (April 1998)

#### 1998

#### Special Report #A

Results of 1998 validation study: Analysis of concurrence between Core Indicators data abstracted by dialysis facility staff and ESRD Network staff (February 1999)

#### Supplemental Report #1

\*Comparison of demographic and selected intermediate outcome measures for health maintenance organization (HMO) and fee-for-service (FFS) adult in-center hemodialysis patients (February 1999)

#### Supplemental Report #2

\*Comparison of selected intermediate clinical measures by years on dialysis (April 1999)

#### 1999

#### Supplemental Report #1

\*Vascular access for in-center hemodialysis patients: Preliminary findings (February 2000)

#### Supplemental Report #2

Network trends, 1993-1999 (July 2000)

#### **Supplemental Reports (continued)**

#### 2000

#### Supplemental Report #1

\*A study of pediatric (≥ 12 and < 18 years old) in-center hemodialysis patients: Results from the 2000 End Stage Renal Disease (ESRD) Clinical Performance Measures Project (January 2001)

#### Supplemental Report #2

\*Hemodialysis CPMs IV and V: Results from the pilot-test of the facility questionnaire, 1999-2000 (March 2001)

#### Supplemental Report #3

\*Comparison of facility-reported, calculated, and prescribed dialysis adequacy values: Results from the 2000 End-Stage Renal Disease (ESRD) Clinical Performance Measures (CPM) Project (June 2001)

#### 2001

#### Supplemental Report #1

\*Intermediate outcomes for adult Asian in-center hemodialysis patients in the U.S.: Results from the 2001 End Stage Renal Disease (ESRD) Clinical Performance Measures Project (December 2001)

#### Supplemental Report #2

\*Longitudinal analysis of pediatric (≥ 12 and < 18 years old) incenter hemodialysis patients: Results from the 2001 End-Stage Renal Disease (ESRD) Clinical Performance Measures Project (February 2002)

#### Supplemental Report #4

\*Intermediate outcomes for adult in-center hemodialysis patients in the U.S. by cause of ESRD: Results from the 2001 End-Stage Renal Disease (ESRD) Clinical Performance Measures Project (March 2002)

#### Supplemental Report #5

Intermediate outcomes for adult peritoneal dialysis patients in the U.S. by cause of ESRD: Results from the 2001 End-Stage Renal Disease (ESRD) Clinical Performance Measures Project (March 2002)

\* Supplemental Report either has been published or is being developed into a manuscript to be published in either a peer-reviewed journal or in a smaller journal

#### 2002

#### Supplemental Report #1

\*Results from the 2002 end-stage renal disease (ESRD) Clinical Performance Measures (CPM) supplemental questionnaire: Impact of specialization of primary nephrologist on care of pediatric hemodialysis patients. (February 2003)

#### Supplemental Report #2

\*Analysis of intermediate outcomes for adult Hispanic in-center hemodialysis patients: Results from the 2002 end-stage renal disease (ESRD) Clinical Performance Measures (CPM) Project. (March 2003)

#### Supplemental Report #3

\*Analysis of intermediate outcomes for adult in-center hemodialysis patients with diabetes: Results from the 2002 end-stage renal disease (ESRD) Clinical Performance Measures (CPM) Project (May 2003)

#### Supplemental Report #4

Analysis of intermediate outcomes for adult peritoneal dialysis patients with diabetes: Results from the 2002 end-stage renal disease (ESRD) Clinical Performance Measures (CPM) Project (May 2003)

2004 NATIONAL CPM DATA COLLECTION – NATIONAL AND NETWORK PROFILES for Adult (aged ≥ 18 years) In-Center Hemodialysis Patients

**APPENDIX 7** 

# 2004 NATIONAL CPM DATA COLLECTION - NATIONAL AND NETWORK PROFILES (cont.) for Adult (aged $\geq 18$ years) In-Center Hemodialysis Patients

	1	NDIX 7)	I	ſ			ı	П	ı	ı	ı	1	95
nS	11.9	80	36	9	201.2	157.7	7	ns	81	27.0	94	526	65
Net 18	11.9	83	38	9	189.7	156.7	16	Net 18	87	29.8	94	603	56
Net 17	11.9	82	39	s.	170.3	144.9	13	Net 17	78	26.3	94	470	55
Net 16	11.8	78	40	9	181.2	166.7	11	Net 16	72	24.0	76	460	64
Net 15	12.0	83	34	δ.	189.4	103.6	9	Net 15	82	26.6	93	466	65
Net 14	11.8	79	38	9	181.2	115.9	12	Net 14	83	28.6	95	580	19
Net 13	11.8	77	33	7	219.1	137.1	7	Net 13	18	27.0	96	573	99
Net 12	11.7	08	43	7	186.5	154.9	9	Net 12	75	24.8	95	510	64
Net 11 ]	12.1	81	28	9	189.0	111.6	4	Net 11 N	81	T.72	94	493	99
Net 10	12.0	83	34	v.	220.8	169.3	4	Net 10	82	28.3	95	298	65
Net 9	12.0	08	32	9	200.6	209.2	11	Net 9	74	25.7	94	999	70
Net 8	11.8	08	39	v.	206.1	403.1	*	Net 8	78	25.7	95	572	29
Net 7	11.8	77	36	∞	211.9	235.4	3	Net 7	08	27.3	96	589	99
Net 6	11.9	78	33	7	220.5	102.7	*	Net 6	85	T.72	94	556	99
Net 5	11.9	62	37	9	217.3	178.2	8	Net 5	83	27.0	91	461	69
Net 4	11.8	08	39	7	207.0	108.0	*	Net 4	81	27.0	94	496	65
Net 3	12.0	82	34	7	216.9	183.1	10	Net 3	08	26.3	91	482	73
Net 2	12.0	81	34	∞	232.7	164.7	4	Net 2	79	28.0	92	537	64
Net 1	11.9	81	37	v.	200.7	154.4	4	Net 1	62	26.7	92	495	65
Anemia Mgmt.	Median Hgb (g/dL)	% Pts with Mean Hgb > 11g/dL	% Pts with Mean Hgb 11-12.0 g/dL^	% Pts with Mean Hgb < 10g/dL	Median wkly IV EPO dose units/kg/wk	Median wkly SC EPO dose units/kg/wk	% Pts Rx'd^ SC EPO	Iron Mgmt.	% Pts with Mean TSAT ≥ 20%	Median TSAT %	% Pts with Mean Ferritin ≥ 100 ng/mL	Median Ferritin ng/mL	% Pts Rx'd IV Iron

2004 NATIONAL CPM DATA COLLECTION - NATIONAL AND NETWORK PROFILES (cont.) for Adult (aged  $\geq 18$  years) In-Center Hemodialysis Patients

	$\mathbf{S}\mathbf{\Omega}$	39	81	3.9	3.5
	Net 18	41	85	3.9	3.1
		42	82	3.9	*
	Net 15 Net 16 Net 17	31	82	3.8	3.4
	Net 15	34	82	3.9	3.5
		43	84	3.9	3.8
aricins	Net 13 Net 14	40	83	3.9	3.7
o T CIC (II	Net 12	34	79	3.8	3.7
	Net 11	37	08	3.9	3.5
	Net 10	45	82	3.9	3.5
) IIII (	Net 9	40	78	3.9	3.1
o years	Net 8	43	83	3.9	*
101 Audit (aged = 10 years) III-Center Menioularysis Laucius	Net 7	37	79	3.9	4.0
ruuit (a	Net 6	40	85	3.9	3.6
101	Net 5	33	82	3.8	*
	Net 4	35	77	3.8	3.3
	Net 3	33	77	3.8	3.2
	Net 1 Net 2	40	78	3.9	3.6
	Net 1	. 32	08	3.8	3.7
	Albumin	% Pts with Mean serum albumin ≥ 4.0/3.7g/dL (BCG/BCP)^^ 32	% Pts with Mean serum albumin ≥ 3.5/3.2g/dL (BCG/BCP)	Median serum <b>BCG</b> albumin (g/dL)	Median serum <b>BCP</b> albumin (g/dL)

MBCG/BCP-Bromcresol Green/Bromcresol Purple Laboratory Methods

Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

<sup>\*</sup> Value suppressed because  $n \le 10$ 

## Appendix 8. 2004 ESRD CPM Outcome Comparison Tool – Adult In-Center Hemodialysis Patients – National and Network Data are from October – December 2003.

Enter your Network data from Appendix 8 and use this tool to document and compare your facility outcomes to the national data and your Network data.

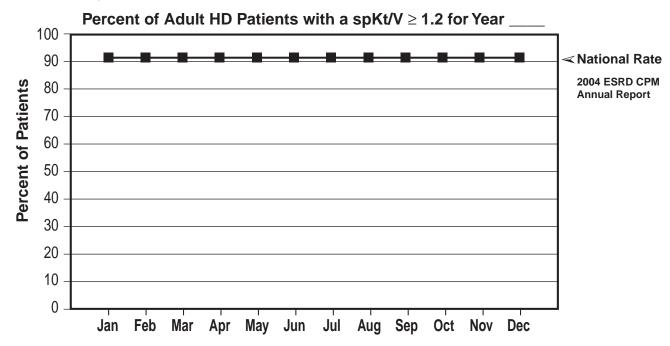
	US	Network	Facility
Adequacy of Dialysis			
Percent of patients with a mean $spKt/V \ge 1.2$	91%		
Mean (±SD) spKt/V	1.53 (± 0.26)		
Mean (±SD) blood pump flow rate (mL/minute)	395 (± 64)		
Mean (±SD) dialysis session length (minutes)	216 (± 30)		
Vascular Access			
Percent of prevalent patients dialyzed with an AVF	35%		
Percent of incident patients dialyzed with an AVF	35%		
Percent of prevalent patients dialyzed with an AV graft	38%		
Percent of prevalent patients dialyzed with a catheter	27%		
Percent of prevalent patients dialyzed with a catheter ≥ 90 days	20%		
Anemia Management			
Percent of patients with mean $Hgb \ge 11.0 \text{ g/dL}$	80%		
Percent of targeted $^{\dagger}$ patients with mean Hgb 11.0 – 12.0 g/dL	36%		
Percent of patients with mean $Hgb < 10.0 \text{ g/dL}$	6%		
Mean (±SD) Hgb (g/dL)	11.9 (± 1.2)		
Mean (±SD) weekly Epoetin dose (units/kg/week)			
IV	271.3 (± 251.8)		
SC	206.2 (± 184.8)		
Percent of patients* prescribed SC Epoetin	7%		
Percent of patients with mean TSAT $\geq 20\%$	81%		
Mean (±SD) TSAT (%)	29.3 (± 12.1)		
Percent of patients with mean serum ferritin concentration $\geq 100 \text{ ng/mL}$	94%		
Mean (±SD) serum ferritin concentration (ng/mL)	596 (± 419)		
Percent of patients prescribed IV iron	65%		
Serum Albumin			
Percent of patients with mean serum albumin $\geq 4.0/3.7$ g/dL (BCG/BCP)	39%		
Percent of patients with mean serum albumin $\geq 3.5/3.2$ g/dL (BCG/BCP)	81%		
Mean (±SD) serum albumin (g/dL)			
BCG	3.8 (± 0.4)		
ВСР	3.5 (± 0.5)		

<sup>†</sup> See appendix 1 for complete definition of targeted patients for this CPM.

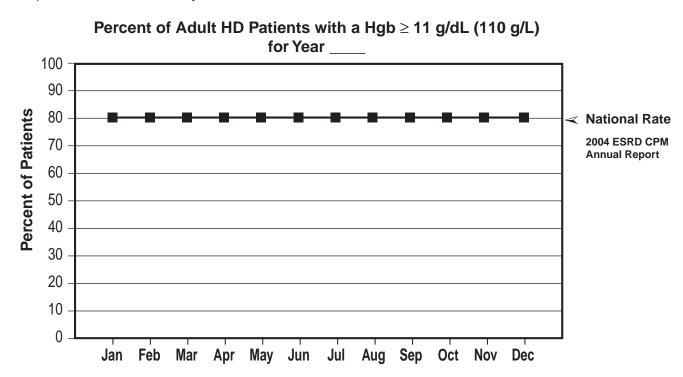
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10. Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

<sup>\*</sup> Among those patients prescribed Epoetin.

Use the following chart to plot monthly the percent of adult HD patients in your unit that have a  $spKt/V \ge 1.2$  (Nation = 91%). Post the chart in the facility for all to see.



Use the following chart to plot monthly the percent of adult HD patients in your unit that have a Hgb  $\geq$  11 g/dL (110 g/L) (Nation = 80%). Post the chart in the facility for all to see.



CUT ALONG THIS LINE

## Appendix 9. 2004 ESRD CPM Outcome Comparison Tool – Adult Peritoneal Dialysis Patients – National Data are from October 2003 – March 2004.

Use this tool to document and compare your facility outcomes to the national data.

	US	Facility
Adequacy of Dialysis		
Percent of patients measured for adequacy at least once during the six month study period		
(both weekly $\mathrm{Kt/V}_{\mathrm{urea}}$ and weekly creatinine clearance measured)	86%	
Percent of CAPD patients with mean weekly $Kt/V_{urea} \ge 2.0$	67%	
Mean (± SD) weekly Kt/V <sub>urea</sub> for CAPD patients	2.28 (±0.64)	
Percent of Cycler patients with a daytime dwell with mean weekly $Kt/V_{urea} \ge 2.1$	59%	
Mean (± SD) weekly Kt/V <sub>urea</sub> for Cycler patients with a daytime dwell	2.29 (±0.60)	
Percent of Cycler patients without a daytime dwell with mean weekly $Kt/V_{urea} \ge 2.2$	56%	
Mean ( $\pm$ SD) weekly Kt/V $_{urea}$ for Cycler patients without a daytime dwell	2.39 (± 0.73)	
Anemia Management		
Percent of patients with mean $Hgb \ge 11.0 \text{ g/dL}$	82%	
Percent of targeted† patients with mean Hgb 11.0 – 12.0 g/dL	39%	
Percent of patients with mean Hgb < 10.0 g/dL	5%	
Mean (± SD) Hgb (g/dL)	12.0 (± 1.3)	
Percent of patients* prescribed SC Epoetin	98%	
Percent of patients with mean TSAT $\geq 20\%$	85%	
Mean (± SD) TSAT (%)	29.9 (± 10.7)	
Percent of patients with mean serum ferritin ≥ 100 ng/mL	88%	
Mean (± SD) serum ferritin concentration (ng/mL)	453 (± 405)	
Percent of patients prescribed IV iron	23%	
Serum Albumin		
Percent of patients with mean serum albumin $\geq$ 4.0/3.7 g/dL (BCG/BCP)	20%	
Percent of patients with mean serum albumin ≥ 3.5/3.2 g/dL (BCG/BCP)	63%	
Mean (± SD) serum albumin (gm/dL)		
BCG BCP	3.6 $(\pm 0.5)$ 3.3 $(\pm 0.5)$	

<sup>†</sup> See appendix 1 for complete definition of targeted patients for this CPM.

Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

<sup>\*</sup> Among those patients prescribed Epoetin.

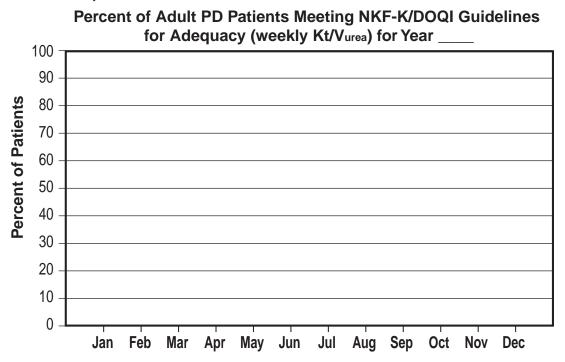
Use the following chart to plot monthly:

The % of adult CAPD patients in your unit that have a Kt/V  $_{urea} \ge 2.0$  (Nation = 67%).

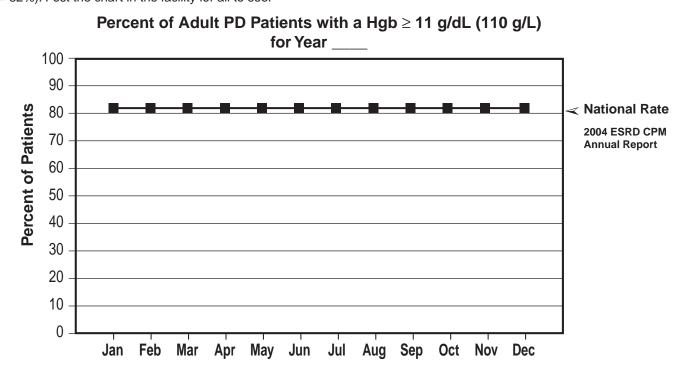
The % of adult Cycler patients with a daytime dwell that have a  $Kt/V_{urea} \ge 2.1$  (Nation = 59%);

The % of adult Cycler patients without a daytime dwell that have a  $Kt/V_{urea} \ge 2.2$  (Nation = 56%).

Post the chart in the facility for all to see.



Use the following chart to plot monthly the percent of adult PD patients in your unity that have a Hgb  $\geq$  11 g/dL (110 g/L) (Nation = 82%). Post the chart in the facility for all to see.



**CUT ALONG THIS LINE**